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## GUEST EDITORIAL

# Generic versus branded medicines

**Bhattacharyya NC\***

Generic medicines are produced by manufacturers other than the original innovator company that holds the patent for a particular pharmaceutical product. Such products can be marketed after the expiry date of the patent or other exclusive rights enjoyed by the original innovator company. A generic medicine contains the same active ingredient as the original product manufactured under patent, with the same dose, route of administration and concentration. It is essential that the generic medicine has the same bioequivalence, quality, performance and intended use for the same disease condition, as the innovator product. The name of the medicine, its appearance and packaging can be different from the original research product with the brand name. Ideally the generic medicine should be marketed with the name of the active ingredient contained in it. As the expenses incurred by the original innovator company for research and development, clinical trials and marketing are generally very high, the company sets a high price tag for the drug during the period of patent rights. Once this period of exclusive right is over, the same drug can be manufactured and marketed by other companies at a much lower price with a generic name.

### **Why Generic products are necessary**

The use of generic products are necessary to reduce cost of treatment and to increase access to healthcare service, particularly in a developing country where the healthcare delivery system is not robust enough, unlike developed countries where the healthcare budget enjoys a significant percentage of the GDP. In order to achieve these objectives, a system of rigorous quality control and safety measures for the pharmaceutical products are essential. In a developing country like ours, the generic products available in the market may greatly vary in quality, because of the lack of clear and specific requirements for generic pharmaceutical products. It has been agreed by various authorities that the bioequivalence and bioavailability of the active ingredient of the generic medicine must be identical or 'interchangeable' with the original innovator product. Only then the generic product will be appropriate clinically as a substitute. The WHO speculated that up to 30 % of the total drug market in some developing countries where the regulatory system is not very active may be counterfeit.<sup>1</sup>

### **The cost factor**

The cost of medicine and other pharmaceutical products, surgical appliances and implant devices as a percentage of total health care expenditure has been rising worldwide, so also in India due to high cost of innovator products. Prescription of generic medicine has been an accepted practice in many western countries including USA and UK, and the proportion of generic prescription in comparison to branded products is gradually rising to reduce the cost of treatment. In some countries it is a part of training for the medical students to learn about generic drug prescription. In our country the procurement price and the retail price of many generic drugs manufactured by reputed pharmaceutical companies vary widely with a high profit margin for the retailers. This adversely affects the users by raising the cost of treatment unnecessarily.

### **Multiplicity of products**

In the Indian pharmaceutical market, there are large numbers of brands for the same pharmaceutical product available in the market to choose from, which causes further confusion in the minds of the users. Mathew, in a study from South India has divided the various types of pharmaceutical products into innovator brands, most-selling generics, least-priced generics and unbranded generics, with the innovator brand being the most expensive and the unbranded generics the least expensive.<sup>2</sup> Most selling generics, also referred to as branded generics by some, are widely available products in the market under various names. The manufacturing and marketing companies try to keep their own identity visible, and compete with each other for increasing their market share. In the process, they offer higher profit to retailers, while spending large amount for promotional activities. Not only the purchasing public but also the physicians and pharmacists get confused whether these are branded medicines or generics.

### **The unbranded generics**

The unbranded generics which are supposed to be the least expensive should be marketed and prescribed by the name of the active ingredients in them. Very often the physicians while prescribing find it difficult to remember the pharmacological name of the active ingredient. The retailer



pharmacists find it more difficult to dispense it as they are confused by the large number of branded generics available in his pharmacy. In the process the pharmacists tend to dispense the product which is sold with the highest profit margin irrespective of the quality. Most of the private pharmacies of our country are not manned by qualified pharmacists, and the persons dispensing the medicines have no knowledge and training regarding prescription of generic medicines. As a result of this they are guided by the representatives of the manufacturing companies and marketing agents. Although there may be difference in the efficacy of various branded generics available in the market, physicians tend to prescribe drugs marketed by reputed pharmaceutical companies, without noticing that the drug may have been manufactured by lesser known manufacturers.<sup>2</sup>

In case of unbranded generics, unattractive packaging and lack of promotional activities leads to less popularity of the products. The physicians also feel it cumbersome to write fixed dose combination drugs with the generic names. Particularly, in a busy government hospital where the outpatient clinics are always over-crowded, it will take lot of extra time for the prescribing physicians to write fixed dose combination drugs by generic names. Added to this, in Indian Medical Council Professional Conduct, Etiquette and Ethics Regulations 2002, it is clearly mentioned that “Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs”.<sup>3</sup>

### Studies from India

There have been many published works from various countries of the world dealing with the efficacy, popularity, prescribing habits of physicians and benefits of dispensing generic drugs. There are also some such studies published from India analyzing the various aspects of use of generic medicine. Das et al, in a study conducted in West Bengal found that generic drugs sold by fair price medicine shop established in the government run hospitals under Public Private Partnership (PPP) mode, have better acceptability to the patients.<sup>4</sup> Singal et al in their study observed that the government must take up generic promotional activities, create awareness on use of generic medicine to build confidence among physicians, pharmacists and the users, make the generic medicine freely available in the market with lower price tag and assured quality.<sup>5</sup>

### Government initiative:

More use of generic medicine is going to ease the ultimate healthcare expenditure of the government. Government initiatives are to be directed towards educating the healthcare professionals to create more awareness about generic drugs. Some knowledge about generic medicine and method of writing generic prescription should be taught during the undergraduate medical course. Similarly students of pharmacy course should also have some knowledge about generic medicine. Some attention is also required for the large number of untrained dispensers working in the pharmacies throughout

the country. At the same time strict quality control and market regulations are necessary. All states must have adequate set up for modern and well equipped drug testing laboratories to standardize the efficacy of the generic drugs available in the market. There has to be some mechanism to reduce the wide difference between procurement price and retailer's price, so that the public gets the benefit. To avoid confusion, something has to be done to restrict the innumerable branded generics available in the market. Preparation of an all inclusive essential drug list (EDL) for all government health establishments and making these drugs available in their true generic form with the minimum price tag will help in reducing health care expenditure. Meanwhile, non-essential details like doctors writing prescriptions in capital letters may take a back seat for the time being.

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## REVIEW PAPER

# The changing landscape of induction chemotherapy in head and neck cancers

Negi Preety<sup>1</sup>, Srivastava H<sup>2</sup>, Kingsley PA<sup>3</sup>

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### ABSTRACT

*In an attempt to improve the survival in locally advanced head and neck carcinomas, varying sequencing of treatment modalities namely surgery, radiation therapy and chemotherapy has been tried. Although concurrent chemoradiotherapy is the standard of care for these patients, induction chemotherapy is considered an effective alternative approach by head and neck oncologists worldwide. Induction chemotherapy continues to be actively pursued because of its potential to control locoregional disease, possible eradication of micrometastasis and organ preservation without jeopardizing overall survival. In spite of the positive impact of docetaxel-based induction regimens, its direct comparison with the standard treatment failed to show superior results in terms of survival and completion of planned definitive radiation treatment. Several clinical trials have served to clarify the role of induction chemotherapy before definitive treatment in head and neck cancer, still the data remains controversial and warrants randomized controlled trials to ensure that most effective therapy is delivered with subsequent improvement in survival for these patients. This review summarizes key milestones in the evolution of induction chemotherapy in head and neck carcinoma.*

**Keywords:** Taxanes; squamous cell carcinoma.

### INTRODUCTION

The treatment of patients with locally advanced head and neck carcinoma (LAHNC) is evolving rapidly. In addition, manuscripts based on author's assessment of the paper's relevance to the topic under consideration were included in this review.

#### The Evolution of Induction Chemotherapy in Head and Neck Cancers

In early 1990s, the incorporation of induction chemotherapy

(ICT) before definitive radiotherapy (RT) was extensively investigated as an organ preservation approach particularly for laryngeal or hypopharyngeal carcinomas that would otherwise be managed with surgical approach leading to devastating effect on patient's quality of life.<sup>1</sup> The landmark Veterans Affairs Laryngeal Study Group provided strong evidence supporting the superiority of ICT followed by definitive RT compared with laryngectomy and adjuvant RT in terms of excellent laryngeal preservation (64%) without compromising overall survival (OS).<sup>1</sup> Further building upon this, long-term results defined 4 cycles of ICT followed by locoregional treatment to be reserved for patients with inoperable LAHNC only (p=0.04).<sup>2</sup>

The largest [MACH-NC (Meta-Analysis of Chemotherapy in Head and Neck Cancer)] demonstrated significant survival advantage (4% at 5 years) in patients receiving chemotherapy, with an even greater benefit (8% at 5 years) observed in patients undergoing concurrent chemoradiotherapy (CCRT).<sup>3</sup> The updated analysis showed absolute survival benefit of

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6.5% at 5 years (HR 0.81, 95% CI 0.78-0.86,  $p < 0.001$ ) with CCRT was confirmed in comparison to RT alone. The interesting results from this update favoured CCRT while ICT failed to show any survival advantage over the standard of care treatment leading to abandonment of ICT.<sup>4</sup>

### Rise of ICT with Taxane-based Regimens

The research groups compared docetaxel, cisplatin, and 5-fluorouracil (TPF)-based regimens with PF regimens thereby reverting our focus towards ICT in the hope of achieving improved outcomes for these patients.<sup>5</sup> In TAX 323 trial, the addition of docetaxel significantly improved median progression-free survival (PFS) (11.0 vs 8.2 months in the TPF group vs PF group;  $p=0.007$ ) and a median OS (18.8 months in the TPF group vs 14.5 months in the PF group)<sup>6</sup> TAX 324 trial results reported that despite a better LRC ( $p = 0.04$ ) and median OS (71 vs 30 months;  $p = 0.006$ ) with TPF regimen.<sup>7</sup> The long-term results observed that survival benefit with TPF continues well beyond 2 years of the original analysis.<sup>8</sup> Groupe d'Oncologie Radiotherapie Tkte Et Cou (GORTEC) 2000-01 trial reported superior results with TPF in terms of overall response rate (80% vs 59.2%;  $p=0.002$ ) and 3-year actuarial larynx preservation rate (70.3% vs 57.5%;  $p=0.03$ ).<sup>9</sup> This benefit with TPF regimen persisted for 10 years.<sup>10</sup> These landmark studies (TAX 323, TAX 324 and GORTEC laryngeal study) validated the benefit of induction-TPF in terms of OS / PFS, local control, and organ preservation as compared to PF regimen. However, neither of these trials compared ICT with conventional CCRT.

### Impact of ICT on Survival

Here, we refer to two meta-analysis performed by Zhang et al<sup>11</sup> and Kim et al.<sup>12</sup> A meta-analysis of five randomized controlled trials described herein directly addressed this important question by comparing ICT followed by CCRT versus CCRT alone.<sup>13-17</sup> The investigators found neither statistically significant differences between the two arms regarding OS and PFS, nor any differences as to the incidence of locoregional recurrence rate. They observed a decrease in DM rate (RR=0.58, 95% CI 0.39-0.85;  $p=0.006$ ) in the ICT group but this benefit came at the cost of significantly increased risk of grade 3 - 4 febrile neutropenia ( $p=0.0009$ ) and leucopenia ( $p=0.04$ ), compared with CCRT alone. This meta-analysis failed to demonstrate survival benefit following the addition of ICT to upfront CCRT.<sup>11</sup> Recently, a larger meta-analysis of six relevant trials comprising 1,280 patients reached similar conclusions of unsatisfactory outcome in terms of OS ( $p=0.339$ ) for TPF prior to CCRT over CCRT alone.<sup>12</sup>

The two large pioneering randomized controlled trials [PARADIGM and DeCIDE (Docetaxel-Based Chemotherapy Plus or Minus ICT to Decrease Events in Head and Neck Cancer)] needs special mentioning since these trials underscore that CCRT is superior to ICT in LAHNC.<sup>14, 17</sup> The PARADIGM trial<sup>14</sup> reported no difference between the ICT and CCRT alone group in rates of DM (7% vs 11%). DeCIDE trial<sup>17</sup> reported a decrease in DM from 19% to 10%; however,

both studies failed to show an improvement in OS and disease-free survival (DFS) with ICT.

### Concerns Regarding ICT

The added toxicity of this modality might affect compliance to RT in patients with borderline resectable or unresectable head and neck cancer.<sup>18-20</sup> Patil et al<sup>20</sup> reported that 15.8% of patients discontinued ICT after the first cycle. Delay in definitive treatment, interruption of treatment and mortality rate of up to 15.8% are considered an area of major pitfall with ICT.<sup>21,22</sup>

Both these trials underscore that CCRT is superior to ICT followed by CCRT in LAHNC; and hence, the results of these trials should be interpreted with caution.<sup>23</sup>

It is important to bear in mind that CT regimen concurrent with RT following ICT might affect the outcome in LAHNC patients. This issue has not been addressed in clinical trials, with as much worth as it should have received. Majority of the trials have used carboplatin (AUC 1.5) or weekly cisplatin 40 mg/m<sup>2</sup> concurrent with RT.

### Role of ICT in Present Scenario

ICT has been integrated into multimodality approach in an attempt to improve the cure rates with better functional outcomes. ICT results in significant reduction in the incidence of DM with achievement of higher rates of laryngeal preservation that could not be ignored.<sup>24,25</sup> Another reason for attractiveness towards ICT could be the fact that patients whose tumours responded to CT had good response to subsequent RT.<sup>26,27</sup> ICT seems to be a promising approach in certain clinical scenarios such as laryngeal preservation, unfavourable sites and T3 / T4 or N2 / N3 disease.<sup>28-30</sup> Other authors have limited its use to patients with good general condition including performance status 0 or 1, weight loss  $> 10\%$ , absence of severe comorbidities,  $< 70$  years of age.<sup>31</sup> These data suggest that definitive CCRT should remain the standard of care while ICT should be reserved for patient population likely to receive greatest benefit from this strategy.<sup>32,33</sup>

### Conclusions

The debate regarding the role of ICT in head and neck cancer is an open topic for discussion among the oncology fraternity for more than a decade now. The potential advantages of ICT include organ function preservation in advanced laryngeal or hypopharyngeal carcinomas, controlling micrometastatic disease, providing symptom control before initiating RT and allowing rapid tumour shrinkage in an attempt to avoid emergency procedures. However, an important concern limiting its regular clinical use is the absence of survival benefit. Identification of specific group of patients likely to benefit from ICT is the future of personalized treatment of head and neck cancer.

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## ORIGINAL PAPER

# A study of Neurological manifestations in systemic lupus erythematosus

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## ABSTRACT

**Objectives:** To analyze clinical, immunological, electrophysiological and radiological spectrum of the patients of Systemic Lupus Erythematosus (SLE) presented with neurological manifestations in Gauhati Medical College & Hospital, Guwahati. **Materials and methods:** Hospital based prospective study carried out in Neurology department. Diagnosed cases of SLE who presented with neurological manifestations at the time of diagnosis or develop during the course of the disease were included in the study. Subjects undergone detailed clinical, immunological and laboratory analysis & appropriate statistical methods were applied as required. **Results:** A total number of 82 cases were evaluated. Median age of presentation was 22 years with female to male ratio 3.5:1. CNS diseases were predominant in 72(87.8%) and rests were symptoms referable to PNS. Among the CNS diseases most common was seizure in 28(38.9%) followed by acute confusional state, headache, myelopathy, stroke, psychosis. Among PNS diseases, most common was polyneuropathy in 12(63.2%), followed by cranial neuropathy, plexopathy, AIDP and myasthenia gravis. ANA was found to be the most common autoantibody in 81(98.7%) cases followed by Anti-ds DNA. Mean SLEDAI was  $8.9 \pm 5.7$ . Disease activity is significantly more in CNS as compared to PNS diseases. It was found that SLEDAI, values on 4-point liker scale and SLICC/ ACR damage index significantly decreased at 6 months during follow up. **Conclusion:** Neurological manifestations are not uncommon in SLE. They correlate with disease activity, and results in high morbidity if not diagnosed early. It is necessary to detect subclinical NPSLE by having a high index of suspicion, and evaluation by clinical, immunological, neuroimaging and neurophysiological tests.

**Keywords:** Acute confusional state; neurolupus; seizure.

## INTRODUCTION

Systemic lupus erythematosus (SLE) is an autoimmune disease in which organs and cells undergo damage initially mediated by tissue binding autoantibodies and immune complexes.<sup>1</sup> People of all genders, ages and ethnic group are susceptible, but it frequently affects women of child bearing age group. The prevalence is approximately 130/100000 in United States, with African Americans, Hispanic and Asians more frequently affected than non-hispanic whites.<sup>2</sup> In Indian population the prevalence is 3/100000.<sup>3</sup> The nervous system is commonly affected in both children and adults with SLE. It is also associated with a worse prognosis and more cumulative damage in children<sup>4</sup> and adults.<sup>5</sup>

Neuropsychiatric symptoms can be among the earliest manifestations of SLE, and some reports suggest up to 40% of neuropsychiatric symptoms appear during the first year of SLE diagnosis.<sup>4</sup> NPSLE symptoms can be a devastating manifestation of SLE, and a recent study demonstrated a standard mortality ratio of 9.5, markedly with acute confusional state.<sup>5</sup>

Autoantibodies are central for the diagnosis of SLE; however, note that the prevalence of anti-nuclear antibodies in healthy

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subjects may reach 20% at certain ages<sup>6</sup> and many non-SLE patients with mild CNS symptoms, such as weakness or headache, might have weakly positive anti-nuclear antibodies testing. For patients with established SLE, several autoantibodies were found to correlate with neuropsychiatric symptoms: APLA with stroke and vascular dementia, seizures, chorea, headache, and transverse myelitis; anti-ribosomal-P with depression or psychosis; anti-neuronal with cognitive dysfunction and depression; anti-ganglioside antibodies with migraine, acute confusional state, depression, and peripheral neuropathy;<sup>7</sup> yet, none of these antibodies can serve as a definite marker of NPSLE.

NPSLE is not uncommon in India and affects younger age group. Early diagnosis and management of NPSLE is a clinical challenge. During the last few decades, overwhelming efforts were made to elucidate the pathophysiology as well as to improve the classification, diagnosis, and management of NPSLE. This accumulated information has enhanced our understanding and ability to help patients. Our study will help in better understanding the disease pathogenesis, which will help in early diagnosis and treatment of the disease that will lead to decreased mortality and morbidity and reduce the burden of disease in the society.

## MATERIALS AND METHODS

**Study Population:** The present study is a prospective single centre hospital based study which was undertaken at the Department of Neurology, Gauhati Medical College and Hospital, Guwahati, Assam from October 2015 to September 2017.

**Selection of the Cases:** The cases for the present study were selected from the Neurology outpatient and inpatient departments as well as from other departments of Gauhati Medical College and Hospital who sought referral for such cases.

**Inclusion Criteria:** (i) Any diagnosed SLE patient presented with neurological symptoms and (ii) Any patient presenting with neurological symptoms that are fulfilling the A.C.R diagnostic criteria of SLE.

**Exclusion Criteria:** Patients having neurological manifestations which can be explained by other concomitant diseases.

All included cases were subjected to a detailed clinical history and clinical examination.

- Investigations including serological, radiological and electrophysiological were done as per clinical symptoms.
- Immunological parameters were analysed as per standard protocol.
- Diagnosis of SLE made by applying the Systemic Lupus International Collaborating Clinics (SLICC) group revised ACR SLE classification criteria 2012.<sup>6</sup>
- Patients were put in various clinical syndromes as per American College of Rheumatology (ACR) case definition and classification criteria for 19 Central Nervous System

(CNS) and Peripheral Nervous System (PNS) syndromes.

- Seizures are classified as per ILAE 2017 classification of seizures.
- Disease activity was measured by the SLE disease activity index (SLEDAI)<sup>8</sup> in 1<sup>st</sup> visit and 6 months follow-up. Patients were categorized according to their disease activity score into three groups: mild (<10), moderate (10-20), severe (20).<sup>9</sup>
- Organ damage was assessed by the Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC-ACR) Damage Index (SDI)<sup>10</sup> at time of 1<sup>st</sup> visit and after 6 months.
- A four-point Likert scale was used to assess the clinical outcome of every NP event between the first visit and re-assessment (1-worsening of symptoms, including death; 2-no change; 3-improvement of symptoms; 4-resolution of symptoms). Likert scales have been previously used by other groups as physician-reported outcome in NP SLE studies.<sup>11</sup>

## Statistical analysis:

Statistical analysis was done using Statistical Package for Social Sciences (SPSS) software version 16. Data were presented as mean, standard deviation, median and percentage. The p-value was considered significant if <0.05.

## RESULTS

A total of 82 cases were included in the study. Median age of presentation was 22 yrs with most common age-group 10-20 yrs. Most of the cases were females (78%) with F: M ratio was 3.5:1. Mean duration of first neurological symptom from diagnosis of SLE was 17.7 ± 20.1 months. CNS diseases were predominant manifestation in 72 (87.8%) and rest were symptoms referable to PNS.

**Table 1** Neurological manifestations

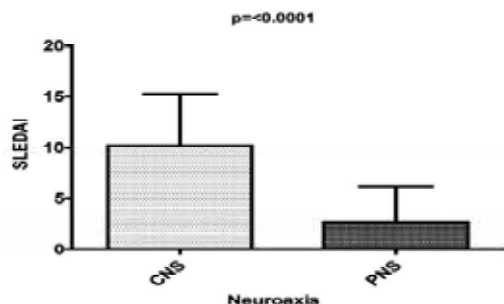
CNS		PNS	
Diseases	No (%) n=72	Diseases	No (%) n=19
Seizures	28 (38.9)	Cranial neuropathy	4 (21.1)
Acute confusional state	17 (23.6)	Polyneuropathy	12 (63.2)
Psychosis	4 (5.6)	Plexopathy	1 (5.3)
Stroke	6 (8.3)	Acute inflammatory demyelinating polyradiculoneuropathy (AIDP)	1 (5.3)
Headache	9 (12.5)	Myasthenia gravis	1 (5.3)
Myelopathy	8 (11.1)		

Common autoantibodies that are known to be associated with SLE were studied. ANA was found to be the most common autoantibody occurring in 81(98.7%) cases, followed by Anti-dsDNA (**Table 2**). One patient with ANA negativity was found to have positive anti-dsDNA. Because of resource poor setting, APLA was studied only in 34 cases and found to be positive in 19(55.9%), among this anticardiolipin antibody in 11(32.4%) followed by lupus anticoagulant 6(17.6) cases. Both antibodies were found in 2(5.9%) cases.

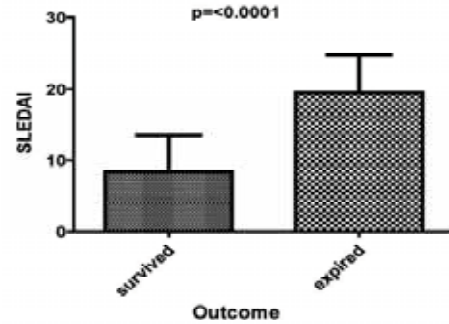
**Table 2** Immunological parameters

Antibody	Cases No. (%) n=82
ANA	81 (98.7)
Anti-dsDNA	67 (81.7)
Anti Sm	31 (37.8)
Anti Ro-52	28 (34.1)
Anti RNP	37(45.1)
Anti Ro (SS-A)	44 (53.7)
Anti La (SS-B)	8 (9.8)
Anti Histone	28 (34.1)
Anti scl-70	1 (1.2)
Anti nucleosome	44 (53.7)
Anti mitochondrial (AMA-M2)	18 (22)
Anti Ribosomal-P	43 (52.4)
Antiphospholipid (APLA) {Done in 34 cases }	19 (55.9)

Mean SLEDAI was  $8.9 \pm 5.7$ . Highest mean SLEDAI was found in stroke followed by seizures. All the patients had mild (0-10) to moderate (11-20) disease activity. Mean SLEDAI was significantly more in CNS as compared to PNS diseases (**Figure 1**). Majority of patients improved and only 5% expired due to intercurrent illness. Patients who expired had significantly high SLEDAI as compared to those who survived (**Figure 2**). 69 patients turned up for regular follow-up and we could compare SLEDAI, values on 4 point likert scale, and SLICC/ACR damage index at time of discharge and 6 month follow-up (**Figure 3,4,5**).



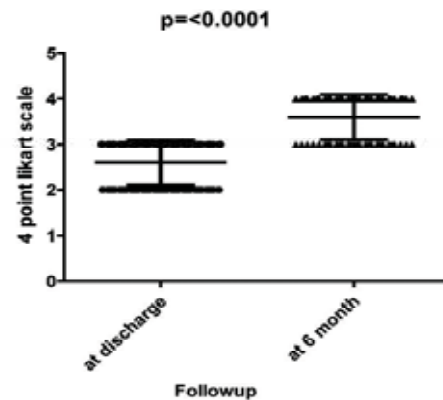
**Figure 1** Comparison of SLEDAI between CNS and PNS diseases



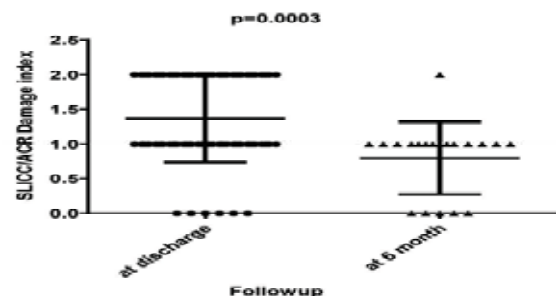
**Figure 2** Comparison of SLEDAI with outcome



**Figure 3** Comparison of SLEDAI in follow up



**Figure 4** Comparison of 4 point likert scale in followup



**Figure 5** Comparison of SLICC/ACR damage index in follow up



## DISCUSSION

Cases are classified according to American college of rheumatology nineteen case definitions for neuropsychiatric SLE (NPSLE) syndrome.<sup>12</sup> CNS was commonly involved as compared to PNS which correlates with previous study.<sup>9,10</sup> Seizure can occur in SLE in any time of disease course and any semiology can occur. In our cases most common semiology was found to be generalized tonic-clonic seizure which correlates with the recent study of Kakati S et al done in north east India.<sup>11</sup> Due to application of strict exclusion criteria, we have ruled out infective and metabolic causes of seizures. However, in many of the cases, we could not ascertain the definite cause for it, due to financial constraint for further investigations. One (1.2%) case of AIDP was found in our study. The prevalence of SLE in AIDP or GBS has been reported to be 0.6-1.7% in literature,<sup>13</sup> which correlates with our study. In a present study one case of myasthenia gravis (MG) was found which is a rare association described in the literatures. A case series by Jallouli et al<sup>14</sup> showed the prevalence of myasthenia gravis 1.3% in SLE cases, which correlates with our study. The frequency of myasthenia gravis in our study is higher than in general population<sup>15</sup> as our study is hospital based which may not reflect whole population.

Most common antibody found in our patients was ANA which correlates with most of the studies from India and all over the world. A study by Malaviya et al<sup>3</sup> compared case series on SLE from different regions of India and found ANA in more than 96% of cases, which correlates with our study. Other studies from India like study by Saigal et al<sup>16</sup> showed 65%, Malaviya et al<sup>3</sup> 55% and Santhanam et al<sup>17</sup> 45% anti-dsDNA positivity in SLE. dsDNA antibodies rise in active disease and in the evolution of lupus nephritis in most patients.<sup>18</sup> As in our study most of the cases are of CNS disease having high disease activity index (described further) and also associated with lupus nephritis; therefore large number of anti-ds DNA positivity found in comparison to available literatures in India.

Regarding disease activity (SLEDAI and SLICC/ACR damage index), most of our cases have mild disease, which is comparable with study by C Magro-Checa et al.<sup>8</sup> It contradicts the study by Kakati et al in which most of the cases had severe disease activity. This is because of higher number of other organ involvement in their study. SLEDAI was significantly higher in CNS as compared to PNS disease in our study. Study by Kampylafka et al showed statistically significant correlation between high disease activity index and CNS manifestation.

In our study majority of cases improved and only 5% expired due to intercurrent illness. We compared SLEDAI between expired and survived and found that disease activity was significantly higher in cases who expired as compared to who survived. Previous studies refer that higher the score more severe is the manifestations.<sup>19,20</sup> On follow up, we found significant decrement in values of SLEDAI, SLICC/ACR

damage index and Likart scale at 6 months, suggestive of improvement. A study by C Magro-Checa et al<sup>8</sup> showed better clinical outcome and a meaningful improvement in NPSLE than non-NPSLE events which is similar to our study. We propose that these findings may be related to reversibility of brain inflammation/dysfunction after starting immunosuppressive therapy as well as to spontaneous decrease of disease activity

## CONCLUSION

Neurological manifestations are not uncommon in SLE and can affect different neuroaxis. It can occur in the absence of either serologic activity or other systemic disease manifestations. They correlate with disease activity, and results in high morbidity if not diagnosed early. Studies attempting to link NPSLE to underlying SLE-specific pathophysiological processes are ongoing. It is necessary to detect subclinical NPSLE by having a high index of suspicion, and evaluation by clinical, immunological, neuroimaging and neurophysiological tests.

**Conflict of interest:** None declared.

**Ethical clearance:** Taken.

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ORIGINAL PAPER

# Prevalence of hypothyroidism in chronic kidney disease: a single centre cross-sectional study

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## ABSTRACT

**Background:** The kidney normally plays an important role in the metabolism, degradation and excretion of thyroid hormones. Chronic kidney disease (CKD) affects the hypothalamus pituitary thyroid axis and peripheral metabolism of thyroid hormone and thus affects thyroid function in many ways. Despite considerable overlap in the symptoms related to hypothyroidism and advanced chronic kidney disease, relatively little is known about the prevalence of thyroid abnormalities in persons with CKD. In patients with end-stage renal disease, it has been suggested that primary hypothyroidism may be more common in patients with end stage renal disease (ESRD) compared with the general population. Thus this study was conducted to estimate the prevalence of hypothyroid in CKD. **Objectives:** To study the prevalence of hypothyroid in CKD and to see if prevalence increases with advancement of CKD stage. **Materials and methods:** This study is a Cross-Sectional study that was conducted among nondialytic CKD patients attending Nephrology OPD of GMCH from March 2014 to Feb 2016. Out of 1742 CKD patients, 280 patients who met the study criteria were included in the study. Demographic features (age and sex) and medical history of each patient were noted at the time of diagnosis. **Results:** The mean age of patients with overt hypothyroid was 59.64 years, in sub-clinical hypothyroid group was 58.14 years, and in patients with normal thyroid function was 55.51 years. We observed that prevalence of hypothyroidism was increased in patients with reduced GFR, and it increases as estimated glomerular filtration rate (eGFR) decreases ranging from 13.33% in stage 2 to 35.55% in ESRD (end stage renal disease). We also found that 68.8% of hypothyroids have sub-clinical hypothyroidism. **Conclusion:** This study concludes that prevalence of hypothyroid in CKD is more than that of general population and it further increases as eGFR decreases.

**Keywords:** Hypothyroidism; CKD; end stage renal disease; sub clinical hypothyroid

## INTRODUCTION

The thyroid produces hormones (T3 and T4) have many actions including metabolism, development, protein synthesis and the regulation of many other important hormones. The kidney normally plays an important role in the metabolism, degradation and excretion of thyroid hormones. CKD affects the hypothalamus pituitary thyroid axis and peripheral metabolism of thyroid hormone and thus affects thyroid function in many ways.

Thyroid stimulating hormone (TSH) is disturbed in uraemia and the TSH response to the hypothalamic thyrotrophic releasing hormone (TRH) is reduced.<sup>1,2</sup> CKD affects the thyroid function by lowering levels of circulating the thyroid hormones, disrupting metabolism and elimination of thyroid hormones<sup>3</sup> and affect the storage of iodine in thyroid gland.<sup>4</sup> The concentration of serum iodine in patients with CKD is higher due to lower iodine clearance caused by reduced glomerular filtration. Elevated levels of serum inorganic iodine in patients with CKD may potentially block thyroid hormone synthesis (Wolf-Chaikoff effect), which can explain higher prevalence of diffuse goitre and hypothyroidism in these patients.<sup>5</sup> Despite considerable overlap in the symptoms related to hypothyroidism and advanced chronic kidney disease, relatively little is known about the prevalence of thyroid abnormalities in persons with CKD. In patients with end-stage renal disease, it has been suggested that primary hypothyroidism may be more common in patients with

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ESRD compared with the general population.<sup>5</sup> Thus this study was conducted to estimate the prevalence of hypothyroid in CKD.

## MATERIALS AND METHODS

A Cross-Sectional study was conducted among nondialytic CKD patients attending nephrology OPD of GMCH from March 2014 to Feb 2016 to investigate for hypothyroid. A total of 1742 CKD patients attended nephrology OPD during study period. Out of 1742 CKD patients, 280 patients who met the study criteria were included in the study. Demographic features (age and sex) and medical history of diabetes mellitus, hypertension and CVD of each patient were noted at the time of diagnosis.

CKD was defined on the basis of MDRD formula. Overt hypothyroidism would be defined by a TSH >5.5 mIU/L and Free T4 <0.89 ng/dl with clinical symptoms. Subclinical hypothyroidism would be defined by a TSH >5.5 mIU/L and Free T4 >0.89 ng/dl (the lower limit of the normal range).

### Inclusion Criteria

- All CKD patients (>18 years of age) not requiring dialysis
- TSH levels >5.5 mIU/L

### Exclusion Criteria

- Age < 18yrs
- Patient who were on thyroid function affecting drugs like, lithium and high-dose steroids, and pregnant women were excluded from the study
- All secondary cases of hypothyroidism and subjects in whom kidney functions could not be estimated due to missing serum creatinine values or those in whom thyroid stimulating hormone (TSH) or Free T4 levels were not available.
- Patients on dialysis

## RESULTS

A total of 1742 non-dialytic CKD patients had attended the Nephrology OPD during the study period. Out of 1742, two hundred and eighty patients met the study criteria and were finally included in the study. The mean age of patients with overt hypothyroid was 59.64 years, in sub-clinical hypothyroid group was 58.14 years and in patients with normal thyroid function was 55.51 years. When age in hypothyroid group (overt and sub-clinical) as a whole is compared with euthyroid group, the difference was statistically significant ( $p=0.023$ ). Among the hypothyroid patients, 12% were males and 26% were females. The mean age of the patients is shown in Table 1 and Table 2.

**Table 1** Comparison of mean age

Condition	Mean age
Overt hypothyroid	59.64
Sub-clinical hypothyroid	58.14
Euthyroid	55.51

**Table 2** Sex distribution

Sex	Hypothyroid (n=45)		Euthyroid (n=235)	
	Number	Percentage	Number	Percentage
Male	24	53.33%	175	74.46%
Female	21	46.66%	60	25.53%

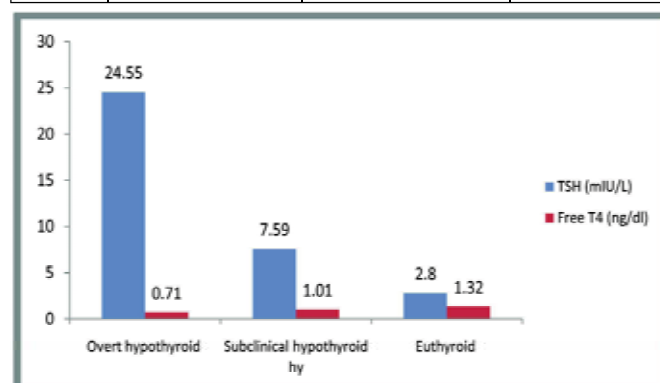
The mean TSH in overt hypothyroid group was 24.55 mIU/L, in sub-clinical hypothyroid was 7.59 mIU/L, whereas in euthyroid group was 2.8 mIU/L. When TSH was compared between hypothyroid patients overall, with euthyroid, the difference was significant ( $p < 0.0001$ ).

The difference in Free T4 between hypothyroid and euthyroid was also statistically significant ( $p < 0.0001$ ).

Table 3 and Figure 1 shows mean TSH and FT4.

**Table 3** Mean TSH and FT4 in hypothyroid cases

	Hypothyroid	Euthyroid	p value
TSH	12.86±9.78	2.80±1.33	<0.0001
FT4	0.92±0.17	1.32±0.26	<0.0001



**Figure 1** Comparison of mean TSH and FT4 between groups. We observed that prevalence of hypothyroidism was increased in patients with reduced GFR, ranging from 13.33% in stage 2 to 35.55% in ESRD. We found that 68.8% of hypothyroids have sub-clinical hypothyroidism.

When we compared prevalence of hypothyroid in stage 5 CKD to stage 2 CKD, we found that it was significantly higher in stage 5 CKD ( $P = 0.05$ ). Similarly we compared prevalence of hypothyroid in stage 3 CKD to stage 4 and stage 5 CKD, and it was significantly higher in stage 4 ( $p = 0.021$ ) and stage 5 CKD ( $p = 0.005$ ).

**Table 4** Prevalence of hypothyroid in different CKD stages

CKD stages	Overt hypothyroid (n=14)	Sub-clinical hypothyroid n=31	Euthyroid (n=235)
CKD Stage 2	2 (14.28%)	4 (12.90%)	18 (7.65%)
CKD Stage 3	4 (28.57%)	7 (22.58%)	58 (24.6%)
CKD Stage 4	4 (28.57%)	8 (25.8%)	72 (30.63%)
CKD Stage 5	4 (28.57%)	12 (38.7%)	87 (37.02%)

## DISCUSSION

The mean age of patients with hypothyroid in our study was 58.64 years, while in a study by chonchol et al,<sup>6</sup> the mean age was 57.9 years. Also in our study 46.66% % of patients with hypothyroid were female, while in another study by Lo et al<sup>7</sup> 52% of patients were female.

In our study, we found an increased prevalence of hypothyroidism in persons with reduced estimated GFR, independent of age and gender. In addition, with progressively lower GFR there was an increased likelihood of hypothyroidism. In our study we found that the prevalence of CKD in non-dialysis requiring population increases from 13% in patient with GFR > 60, to 35% in patient with GFR < 15. Also chochol et al<sup>6</sup> reported increase in prevalence from 11% (GFR>60) to 23% (GFR < 15). According to a study in India among ESRD patients, prevalence of subclinical hypothyroidism was 24.8 %.<sup>8</sup> A study by Ng et al<sup>9</sup> in peritoneal dialysis (PD) patients of Taiwan reported that 98(80.3 %) were having euthyroidism; 19(15.6 %) subclinical hypothyroidism; and 5(4.1 %), subclinical hyperthyroidism.<sup>9</sup> A study among HD patients in western Nepal showed the combined prevalence of subclinical and clinical hypothyroidism in 26.6 % patients.<sup>10</sup> Higher rate of thyroid dysfunction in CKD patients as observed in our study may also be due to high prevalence of thyroid autoimmunity in study population, excess iodine nutrition or iodine deficiency, and the inclusion of subjects with non-thyroidal illness.<sup>11,12</sup>

We observed decreasing trend for free T3 and free T4 levels (though the decrease were not significant) and increasing trend for TSH level (significant rise) across CKD stages 3–5, which suggest that TSH level increases with the progression of renal impairment (which is indicated by a decrease in GFR).

## CONCLUSION

Thyroid dysfunction is common in CKD patients, as compared to person with normal kidney function. This study reveals a significant association between CKD progression and thyroid dysfunction. Hence, high degree of clinical suspicion is needed to diagnose and treat hypothyroidism in CKD.

**Ethical Clearance:** Taken.

**Conflict of Interest:** None.

**Source of Funding:** None declared.

**Contribution of Authors:** The study was conceived and designed by Dr. PJ Mahanta and Dr. M Sharma; data collection and analysis by Dr. Bishal Agarwalla. All liabilities pertaining

to claims relating to the content of this article will be borne by the authors.

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## ORIGINAL PAPER

# Predictors of respiratory failure in acute organophosphorus compound poisoning

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### ABSTRACT

**Introduction:** Poisoning with Organophosphorus (OP) compounds is a common toxicological emergency in an agricultural country like India because of its ease of availability. Fatality in organophosphorus toxicity is mostly due to respiratory failure and cardiovascular collapse. Studies have shown that respiratory failure is one of the most common complications in the acute stage. **Objectives:** The aim of this study was to assess the effectiveness of Glasgow Coma Scale (GCS), Poisoning Severity Scale (PSS) and Peradeniya Organophosphorus Poisoning (POP) Score in predicting the development of acute respiratory failure following Organophosphorus compound poisoning. **Materials and methods:** A prospective, observational study was carried out over a period of one year from July 2017 to June 2018. The diagnosis was based on history of exposure to organophosphorus compound, along with symptoms and clinical signs of cholinergic crisis. Patients were followed up for 24 hours after the exposure to OP compound and were examined for development of acute respiratory failure. **Results:** Out of the total 110 patients in the study, 61(55.45%) were males and 49(44.54%) were females. The mean age was  $30.03 \pm 10.242$  years. Twenty-nine (26.36%) patients developed acute respiratory failure. Patients with GCS less than 10, PSS of 3 or more and POP scale of moderate and severe poisoning more commonly developed acute respiratory failure. **Conclusion:** A low GCS (<10), PSS of 3 or more and a POP grade of moderate and severe poisoning had a strong association with the development of acute respiratory failure.

**Keywords:** Toxicological emergency; Peradeniya OP scale; Poisoning Severity Score.

### INTRODUCTION

Poisoning has become a common social and medical problem worldwide causing significant morbidity and mortality.<sup>1</sup> According to World Health Organization (WHO) reports,

ingestion of pesticides is now the most common method of suicide worldwide.<sup>2</sup>

As per National Crime Records Bureau (2016) report, 27.9% of suicides were committed by consuming poisons in India in the year 2015.<sup>3</sup> Out of all pesticide related deaths, poisoning with Organophosphorous compounds account for two-thirds of all the deaths.<sup>4</sup>

Organophosphorous compounds are organic derivatives of phosphoric and phosphonic acid and a group of cholinesterase inhibiting pesticides. They cause phosphorylation of the enzyme acetylcholine esterase (AChE) rendering it inactive. The binding of the OP compound to the enzyme is irreversible, except with early pharmacological intervention. The inactive, phosphorylated AChE is unable to hydrolyse acetylcholine (ACh) leading to its accumulation in the neuronal synapses and neuromuscular junctions (NMJ).<sup>5</sup> The clinical manifestations of organophosphorus compounds poisoning is due to excessive acetylcholine at the muscarinic and nicotinic receptors resulting in a syndrome of cholinergic crisis.<sup>5</sup>

The early causes of death in acute organophosphorus compound poisoning are due to respiratory failure from CNS depression, bronchospasm, respiratory muscle paralysis or due to ventricular arrhythmias.<sup>6</sup> Respiratory failure, which may be early or late, is the most common complication following OP poisoning.<sup>7,8</sup> Prompt treatment with antidotes and ventilation can reduce the mortality.

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This study was undertaken to identify the factors that help in predicting early respiratory failure and the need for mechanical ventilation in patients with Organophosphorus compound poisoning.

## MATERIALS AND METHODS

This was a prospective, observational study carried out over a period of 1 year from July 2017 to June 2018. A total of 110 patients presenting to Emergency Medicine Department of Gauhati Medical College and Hospital within 24 hours of Organophosphorus poisoning were included in the study. The exclusion criteria were age <18 years, presentation after 24 hours of ingestion of OP compound, patients with known neuromuscular disease, underlying pulmonary disease and OP poisoning in pregnant females.

On admission, primary survey with simultaneous resuscitation and decontamination was carried out, followed by detailed secondary survey with record of demographic factors, time and mode of exposure to OP compound, type of compound patient was exposed to, symptoms, previous medical and surgical illness and any pre-hospital care received.

For all the patients, Glasgow coma scale (GCS), Poisoning Severity Scale (PSS), and Peradeniya Organophosphorus poisoning (POP) score were assessed at the time of admission.

The Poisoning Severity Score (PSS) was developed by European Association of Poison Centres and Clinical

**Table 1** Peradeniya OP Poisoning Scale

Parameter	Criteria	Score
Pupil size	≥2mm	0
	<2mm	1
	Pinpoint	2
Respiratory Rate	<20/min	0
	≥20/min	1
	≥20/min with central cyanosis	2
Heart rate	>60/min	0
	41-60/min	1
	<40/min	2
Fasciculation	None	0
	Present; Generalised/Continuous	1
	Present, generalised and continuous	2
Level of consciousness	Conscious & rationale	0
	Impaired response to verbal command	1
	No response to verbal command	2
Seizures	Absent	0

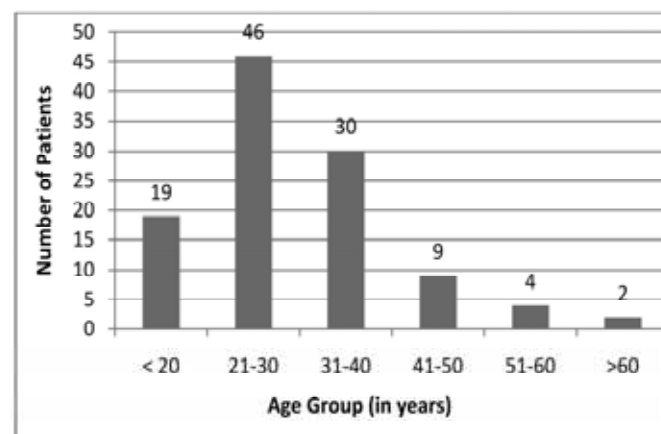
Toxicologists (EAPCCT), International Programme on Chemical Safety (IPCS), and the Commission of the European Union using a collection of clinical signs and symptoms for different organ systems to assign a score of 0 to 4.<sup>9</sup>

The Peradeniya OP Poisoning Scale was introduced by Senanayake et al. in 1993 as a clinical scale to assess the severity of Organophosphorus intoxication.<sup>10</sup> It takes into account the 6 common clinical features of OP Poisoning (**Table 1**). A total of 0-3 is considered as mild poisoning, 4 - 7 as moderate poisoning and 8-11 as severe poisoning.

Relevant blood investigations including arterial blood gas analysis was done in all patients. Patients were followed up for 24 hours after exposure to OP compound and were examined for development of acute respiratory failure. Patients were diagnosed as having early respiratory failure if  $\text{PaO}_2 < 60$  mm Hg and/or  $\text{PaCO}_2 > 50$  mmHg were detected within 24 hours. Categorical variables were analyzed accordingly with the chi-square test or Fisher exact test. For numerical variables, analysis of variance (ANOVA) test was used. For all statistical analyses, a probability ( $p$  value) of less than 0.05 was considered to be statistically significant.

## RESULTS

A total of 110 patients with a history of exposure to organophosphorus compounds presenting within 24 hours were evaluated in the study. Out of the total study population, 29(26.36%) patients developed early respiratory failure, i.e., respiratory failure in the first 24 hours. The mean age was  $30.03 \pm 10.242$  years. Majority (41.81%) of the patients belonged to the age group of 21-30 years (**Figure 1**). 61 patients (55.45%) were males and 49(44.54%) were females.



**Figure 1** Bar Diagram showing age wise distribution of patients

The mode of poisoning was intentional in 108(98.18%) patients and only 2(1.18%) patients had accidental exposure to the OP compound. There were no homicidal cases in our study. The most common route of exposure was ingestion in 98.18% and cutaneous in 1.18% of the patients. Fifty-one patients (46.36%) presented within 3 hours and 59 patients (53.63%) presented after 3 hours of exposure (mean  $5.4 \pm 4.60$  hours).

Out of the total 29 patients developing respiratory failure, 18

(62.06%) patients had developed Type 1 respiratory failure while 11 (37.93%) patients had developed Type 2 respiratory failure.

It was found that 54 patients (49.09%) had a GCS between 11-15, 33 patients (30%) had a GCS between 8-10 and 23 patients (20.90%) had a GCS between 3-7. Among the patients developing early respiratory failure 18 patients had GCS between 3-7 and 11 patients had GCS between 8-10. Patients with a GCS between 11-15 did not develop respiratory failure. This was statistically significant with  $p$  value  $<0.0001$  (Table 2).

**Table 2** Distribution of patients with respiratory failure according to GCS

GCS	Total Patients	Patients with respiratory failure	Percentage
11-15	54	0	0%
8-10	33	11	37.93%
3-7	23	18	62.06%

In our study, the mean Poisoning Severity Score (PSS) was  $1.85 \pm 0.993$ . All patients with a PSS of 4 developed respiratory failure whereas 76.92% with a PSS of 3 and 14.81% of patients with a PSS of 2 developed respiratory failure. No patients with a PSS of 0 or 1 developed respiratory failure, which was significant ( $p$  value  $<0.0001$ ). Table 3 shows the distribution of patients according to Poisoning Severity Score.

**Table 3** Distribution of patients with respiratory failure according to PSS

PSS	Total no. of patients	No. of patients with respiratory failure	Percentage
0 (None)	10	0	0%
1 (Minor)	42	0	0%
2 (Moderate)	27	4	14.81%
3 (Severe)	26	20	76.92%
4 (Fatal)	5	5	100%

As per the Peradeniya Organophosphorus Poisoning (POP) scale applied at the time of admission, 49(44.54%) patients had mild poisoning, 52(47.27%) patients had moderate poisoning and 9(8.18%) patients had severe poisoning. All the 9 patients with severe grade of poisoning developed respiratory failure, 20 patients with moderate grade of poisoning developed respiratory failure, while none of the patients with mild grade of poisoning developed respiratory failure (Table 4). This was statistically significant.

**Table 4** Distribution of patients with respiratory failure according to POP scale

POP scale	Total no. of patients	Patients with respiratory failure	Percentage
Mild	49	0	0%
Moderate	52	20	38.46%
Severe	9	9	100%

## DISCUSSION

In this study, age of the patients ranged from 18 to 67 years (mean  $30.018 \pm 10.287$  years). Majority of the patients (41.81%) belonged to the age group of 21-30 years. The findings are similar to the studies done by Shaikh MA and Patil SL.<sup>11,12</sup> Males constituted 55.45% (61 patients) and females constituted 44.54% (49 patients) of the total study population. These findings were similar to studies conducted by Tsai et al<sup>13</sup> and Mutalik et al.<sup>14</sup> However, studies conducted by Dubey et al<sup>15</sup> and Soni et al<sup>16</sup> had a higher majority of female population.

The mode of poisoning was intentional for suicidal attempt in 108(98.18%) patients, whereas accidental in only 2(1.18%) patients. This was similar to observations made by Ahmed et al<sup>17</sup> and Bandhay et al.<sup>18</sup> A high rate of suicidal attempts with organophosphorus compounds can be explained by the fact that it is cheap, easily available and associated with a high fatality. Moreover, accidental and/or occupational exposure of OP compounds may not be always reported due to mild or atypical symptoms. However, Khan et al reported accidental mode of poisoning in 87.3% of cases.<sup>19</sup>

The route of exposure was ingestion in 98.18% of cases while it was inhalation and/or dermal in 1.18% of cases. This is in accordance with suicide being the most common mode of poisoning. The mean time of presentation after exposure was  $5.4$  hours  $\pm 4.60$ . In this study, 51(46.36%) patients presented within 3 hours of exposure, whereas 59(53.63%) patients presented after 3 hours of exposure to OP compound. Out of 110 patients in total, 29(26.36%) patients developed acute respiratory failure within 24 hours after exposure.

Type 1 respiratory failure was observed in 18(62.06%) patients whereas 11(37.93%) patients developed Type 2 respiratory failure. Goswamy et al in their study observed that 79.41% had developed Type 1 respiratory failure and 20.58% had Type 2 respiratory failure.<sup>20</sup> While 49.09% of our patients had a Glasgow coma scale (GCS) of more than 10, 30% had a GCS between 8-10 and 20.90% had GCS less than 8. Out of the 29 patients developing respiratory failure, no patient had GCS between 11-15, while 37.93% had GCS between 8-10 and 62.06% had GCS between 3-7 which is comparable to the studies by Eranaik et al<sup>21</sup> and Soni et al.<sup>16</sup> A low GCS of the patients correlated significantly with the development of respiratory failure.

According to Peradeniya Organophosphorus Poisoning (POP) scale, patients were graded as having mild, moderate or severe degree of poisoning. In our study, 38.46% of patients with moderate poisoning as per POP scale developed respiratory failure whereas 100% of the patients with severe grade of poisoning developed respiratory failure. Patil et al in their study observed that 62.5% of patients with moderate poisoning and 100% of patients with severe poisoning developed respiratory failure.<sup>22</sup> The result shows that the Peradeniya OP poisoning scale is a good predictor of development of respiratory failure and morbidity in these cases.



Patients were also assigned a score based on the Poisoning Severity Score. The mean PSS was  $1.85 \pm 0.993$  which is comparable to the observation made by Akdur et al.<sup>23</sup> All patients with a PSS of 4 developed respiratory failure whereas 76.92% with a PSS of 3 (severe) and 14.81% of patients with a PSS of 2 (moderate) developed respiratory failure. No patients with a PSS of 0 (None) or 1 (Minor) developed respiratory failure. This was statistically significant with a  $p$  value  $< 0.0001$ . Chandrasekhar et al in their study of 100 patients observed that Poisoning Severity Score (PSS) in a good clinical tool is predicting the outcome in acute OP poisoning.<sup>24</sup> Sam et al and Casey et al also observed a significant correlation between the PSS and the outcome, with a higher PSS in the non-survival group.<sup>25,26</sup>

## CONCLUSION

Clinical scoring systems like Glasgow Coma Scale (GCS), Poisoning Severity Score (PSS) and Peradeniya organophosphorus compound Poisoning (POP) scale are useful tools in predicting the development of respiratory failure in patients with acute organophosphorus compound poisoning. A low GCS ( $<10$ ), PSS of 3 or more and a POP grade of moderate and severe had a strong association with development of respiratory failure.

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## ORIGINAL PAPER

# Study of pattern of fatal intracranial hemorrhages

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## ABSTRACT

**Introduction:** A lot of incidents related to the head region could lead to death, but for simplicity's sake, these incidents are mainly of two broad categories- either non-traumatic (natural) or traumatic (violent). Of all the regional injuries, those of head and neck are found to most common and most important. **Material and methods:** In autopsy room Grant Govt. Medical College Mumbai, more cases with intracranial hemorrhages brought for autopsy compared to other medico-legal cases. The present study was conducted over such fatal intracranial hemorrhage cases at Grant Govt. Medical College & Sir J. J. Hospital Mumbai over the period of five months from 1<sup>st</sup> Jan 2017 to 31<sup>st</sup> May 2017. Total 100 autopsies were conducted during study time out of which 80 cases of males and 20 cases of females of fatal intracranial hemorrhage were observed and studied in detail. **Result:** The post-mortem study revealed that males were outnumbered than female and highest number being in the age group of the 21-40 years. Road traffic accidents 37 cases (37%) were responsible for most of them, followed by accidental fall 19(19%), homicidal assault deaths were recorded as the 8 cases (8%). **Conclusion:** Blunt crania-cerebral trauma was the predominant cause of death identified in this study. In natural causes hypertension was the most common cause of intra-cranial hemorrhage. Intracranial hemorrhage was less in death due to drowning and still birth.

**Keywords:** Head injury; fractures skull; road traffic accident.

## INTRODUCTION

Intracranial hemorrhage is one of the major causes of death today in both natural and un-natural cases. If the bleeding is small thin layered it is called hemorrhage and if it is large and space occupying then it is called hematoma.<sup>1</sup> There are many reasons for intracranial haemorrhage of which most common being head injury.<sup>2</sup> Most common cause for head injury in India is road traffic accident followed by fall from height.<sup>3</sup>

Cranio-cerebral injuries or head injuries were one of the most important regional injuries, known to human beings since history. A vehicular accident constitutes mainly two-wheeler accidents as two-wheeler constitutes main vehicle fleet in India.<sup>4</sup> Head is most common site injured in road traffic accident as it is the most prominent and vulnerable part of human body by virtue of its situation and to sustain serious and fatal injuries owing to the great risk of striking the head. Two-wheeler riders especially of scooter are more prone to develop head injury than another victim. The application of blunt force to the head may result in injury to the contents of the skull, either alone or with a fracture of the skull. The extent and degree of an injury to the skull and its contents is not necessarily proportional to the amount of force applied to the head.<sup>5</sup> The aim of present study is to find out the reasons behind Intra-cranial hemorrhages, pattern of different hemorrhages and fractures observed during autopsy. Association of alcohol and other drug addiction with intracranial hemorrhage and fatal head injury was also touched in this study.

This study has aimed to assess the reasons of intracranial hemorrhages in subjects of Mumbai region and also to manner of death.

## MATERIALS AND METHODS

The study was performed on 100 cases referred to the Grant

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Govt. Medical College and Sir J.J. Group of Hospitals, Mumbai within the period from 1<sup>st</sup> January 2017 to 31<sup>st</sup> May 2017. Complete routine autopsies were carried out for all cases with a thorough external and internal examination. Various identification data of the victims, like age, sex, religion, along with place of incidence and time were noted from inquest report accompanying dead bodies. Digital photography was used for some interesting cases. Tissue specimens were sent for histopathology and Viscera samples were drawn for alcohol and toxicology.

## RESULT

A total 100 post mortem cases were studied. Among them 80% were males and 20% were females. Highest numbers of death due to intra cranial hemorrhage victims were due to road traffic accidents that is (37%), followed by fall (19%), followed by railway accident (13%) and Illness (11%) (**Table 1**). Total number of deaths due to natural causes of intracranial hemorrhages was 23% and unnatural causes were 77% (**Figure 1 and 2**).

In males Intracranial hemorrhage following head injury due to road traffic accident was present in 35% cases, in 15% cases due to fall, in 12% cases due to railway accident, in 4% cases due to assault, and in natural causes it is present in 6% cases due to illness and 4% cases due to hypertension (**Figure 2**).

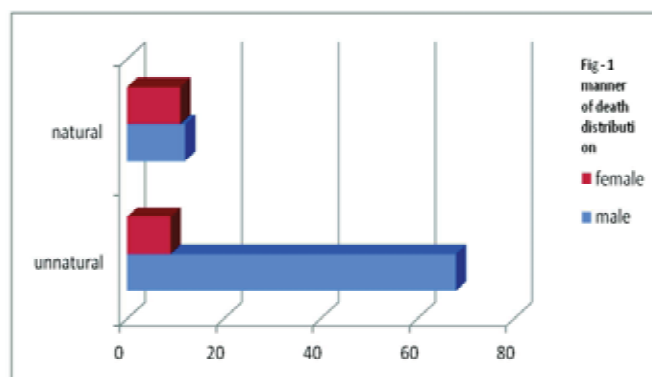
**Table 1** Different reason for ICH

Reason	Frequency
RTA	37
Fall	19
Illness	11
Not unknown	1
Railway accident	13
Assault	8
Hypertension	7
Animals	2
Drowning	1
Still birth	1
<b>Total</b>	<b>100</b>

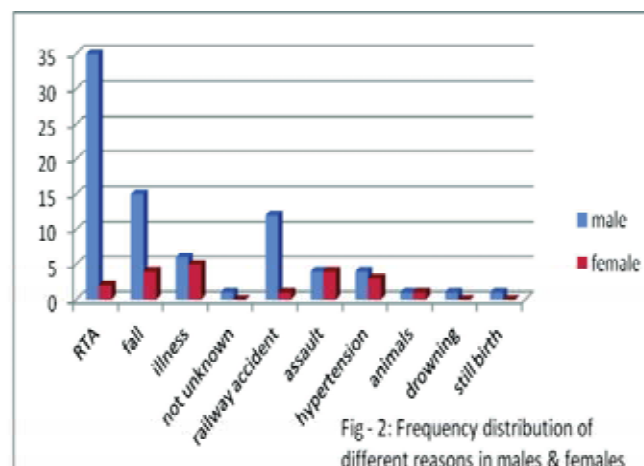
In females Intracranial hemorrhage following head injury due to road traffic accident was present in 2% cases, in 4% cases due to fall, in 1% cases due to railway accident, in 4% cases due to assault, and in natural causes it is present in 5% cases due to illness and 3% cases due to hypertension (**Figure 2**).

As compare to females in males causes of intracranial hemorrhages 68% were unnatural and 12% were natural and in females 9% were unnatural and 11% were natural.

In this study it was seen that under scalp contusion in death due to intracranial hemorrhage was found in 67% in males and 11% in females. In total 78% cases under scalp contusion was found. Extra-Dural hemorrhage was found in total 15% cases of which 14% in males and 1% in females. Subdural



**Figure 1** Manner of death distribution



**Figure 2** Frequency distribution of different reasons in males & females

hemorrhage was found in total 63% cases of which 53% in males and 10% in females. Subarachnoid Hemorrhage was found in total 74% cases of which 63% in males and 11% in females. Intra-cerebral hemorrhage was found in total 18% cases of which 13% in males and 5% in females.

**Table 2** Intra-ventricular hemorrhage

Intra-ventricular hemorrhage		
Sex	yes	No
Male	5	75
Female	5	15
Total	10	90

From **Table 2** it can be seen that under Intra-ventricular hemorrhage was found in total 10% cases of which 5% in males and 5% in females.

**Table 3** History of addiction

History of addiction				
Sex	No addiction	Alcohol	Tobacco	Drugs
Male	55	22	2	1
Female	20	0	0	0
Total	75	22	2	1



From **Table 3** it can be seen that history of addiction was found in total 25% cases which is found only in males and not in females. In this most common addiction was alcohol found in 22% males.

**Table 4** Relation between drug addiction and different intracranial hemorrhage

	Extra-dural hemorrhage	Subdural hemorrhage	Subarachnoid hemorrhage	Intracerebral hemorrhage	Intraventricular hemorrhage
History Of Addiction	yes	Yes	Yes	yes	Yes
No Addiction	10	46	53	14	7
Alcohol	4	14	19	3	3
Tobacco	1	2	1	1	0
Drugs	0	1	1	0	0
Total	15	63	74	18	10

From **Table 4** it can be seen that history of alcohol addiction was seen in 4% cases in extradural hemorrhage, in 14% cases in subdural hemorrhage in 19% cases in subarachnoid hemorrhage and in 3% cases each in intracerebral and intraventricular hemorrhages. History of tobacco addiction was seen in all except in intra-ventricular hemorrhage. History of drug addiction was seen in subdural and subarachnoid hemorrhage.

**Table 5** Most common age group in all types of intracranial hemorrhages.

Age group	Under scalp contusion		Extradural hemorrhage		Subdural hemorrhage		Subarachnoid hemorrhage		Intracerebral hemorrhage		Intraventricular hemorrhage	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
<20	8	1	0	9	4	5	6	3	2	7	0	9
21-40	37	7	8	36	32	12	36	8	5	39	3	41
41-60	23	6	6	23	19	10	22	7	5	24	2	27
61-80	5	7	1	11	7	5	5	7	5	7	3	9
> 81	5	1	0	6	1	5	5	1	1	5	2	4
Total	78	22	15	85	63	37	74	26	18	82	10	90

From **Table 5** it can be seen that under scalp contusion, Extra-Dural hemorrhage, Subdural hemorrhage and Subarachnoid hemorrhage were most commonly seen in age group 21-40 years? Intra-cerebral hemorrhage was found commonly in age group 21-40, 41-60 and 61-80 years. Intra-ventricular hemorrhage was found commonly in 21-40- and 61-80-years age group.

In this study it was found that fracture of skull was found in 7% cases in extra-dural hemorrhages, in 26% cases in subdural hemorrhages, in 33% cases in subarachnoid hemorrhages, in 5% cases in intra-cerebral hemorrhages and in 2% in intraventricular hemorrhages.

## DISCUSSION

Road traffic accident was the most common mode of the fatal head injury. The overall increase in vehicular traffic to the roads is responsible for automobile accidents being the most common mode of fatal injury. Similar findings were noted down in other studies.<sup>5</sup> In present study, linear fracture of skull was the commonest type of skull fracture. Pathak, Vyas and Menon found the similar findings.<sup>6-9</sup>

In this study, Males clearly outnumbered females with male to female ratio as 4:1. Similar findings were observed in other

studies such as Kumar, Patil and Shivkumar.<sup>10</sup> In the age group analysis of the victims, maximum incidence was in age group of 21 years to 40 years and least in group less than 20 and more than 80 years. Similar findings were observed by Kumar, Patil and Shivkumar's studies.<sup>10</sup> This high prevalence of fatal head injury in young age group is because of social and physical activeness of individual from this age group. And they were either students or serviceman who wants to remain outside home and travel through vehicle most of the time.

Hypertension was the most common cause of intra-cranial hemorrhage in natural causes of death. Total deaths due to natural intracranial hemorrhage are 18%, of which 7% are due to hypertension. Scalp injury with skull fracture along with intracranial hemorrhage was the most common presentation of head injury. These findings correlate with the other studies done by Patil and Waz.<sup>11</sup> On autopsy smell of alcohol was perceived in 22% cases. We preserved viscera for chemical analysis in suspected cases. But the reports of such cases are awaited till date. So alcohol contribute as a major risk factor while driving a car or riding motorcycle. In 2% cases tobacco addiction and in 1% cases another drug addiction was present.

## CONCLUSION

The current study was conducted and the data generated were compared in almost all respects with the studies conducted by previous researchers, which recognized males were prone to having fatal head injury and road traffic accidents as the predominant cause of fatal head injury due to blunt trauma and its followed by fall from height as second common cause of intra cranial hemorrhage. Blunt cranio-cerebral trauma was the predominant cause of death identified in this study. These fatalities could be avoidable. In natural causes hypertension was the most common cause of intracranial hemorrhage. Intracranial hemorrhage was less in death due to drowning and still birth.

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**Contribution of Authors:** We declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors.

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## ORIGINAL PAPER

# Profile of burns cases among children treated at a tertiary care hospital

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## ABSTRACT

**Introduction:** Epidemiological data on burns in children can give valuable information to policy makers for developing prevention strategies in reducing the incidence of childhood burns. **Objectives:** To study the Profile, manner and outcome of burns cases among children treated at a tertiary care hospital. **Materials and methods:** A Retrospective observational study was conducted based on medical records of children below the age of 12 years with the diagnosis of acute burns admitted to Jubilee Mission Medical College Hospital during 01-07-2016 to 30-06-2017. **Results:** A total of 169 burn cases were treated during the study period, of which 61 were children below 12 years. Maximum numbers of affected children were from the age group of less than 4 years and 60 cases were of accidental in nature. Scalding was the predominant cause of injuries and often related to cooking practices. No cases were reported with more than 30% burns and there was no mortality. **Conclusion:** Burn injuries can be reduced by bringing about regulations to develop safer cooking practises and educating the community especially the women on safe practises at home and also on first aid measures.

**Keywords:** Accidental burns; Child abuse; homicidal burns.

## INTRODUCTION

The term Burn denotes an injury to the skin or other organic tissue primarily caused by heat or due to radiation, radioactivity, electricity, friction or contact with chemicals.

Over the past several decades incidence of burns, burns related admissions, burns related morbidity & mortality have decreased by nearly 50% due to different legislations, health promotion, appliance design, advanced burn care and a better understanding of fluid resuscitation and aggressive surgical management. Despite all these developments, burns remain a leading cause of morbidity and mortality.<sup>1</sup> Incidence of burn

injuries varies greatly between cultures and it is a global public health problem accounting for an estimated 2,65,000 deaths annually. The majority of these occur in low- and middle-income countries and almost half occur in south East Asia region.

In India over 10,00,000 people are moderately or severely burnt every year.<sup>2</sup> According to most recent data females and males have broadly similar rates for burns but there is a higher risk for females. Along with adult woman, children are particularly vulnerable to burns. Burns are the eleventh leading cause of death of children aged 1 to 9 years and also the fifth most common cause of non-fatal childhood injuries.<sup>2</sup>

Men are likely to suffer from burns in the work places while children and woman are usually suffered in domestic places. In children a major risk is improper adult supervision but a considerable number of burns in children result from child maltreatment also. Even though most of the child hood burns are accidental, child abuse also does occur. Nationally approximately 10% of child abuse cases involve burning, and up to 20% of paediatric burns admissions involve abuse or neglect.<sup>3</sup> A hospital based retrospective study conducted

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in India during the year 1992 – 2017, showed 9.3% burn injuries were secondary to abuse.<sup>4</sup>

Burns represent an extremely stressful experience for both the burn victims and as well as their families. Paediatric burns can have long term physical, psychological, economic and social implications for the patients and their families with on-going treatment, rehabilitation and the need for regular interventions.

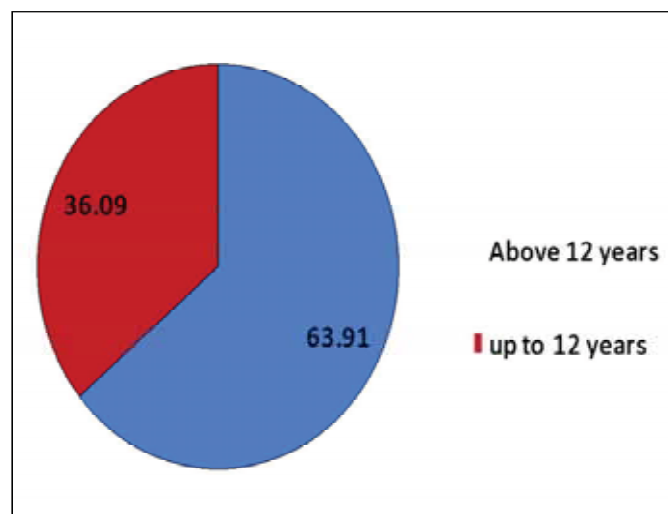
Epidemiological study is an important modality to analyse the cause, magnitude and profile of burn in a particular region and population. Epidemiological data on burns in children can provide vital information for developing prevention strategies, through which the incidence of burns can be reduced. We do not have a recent and reliable data on the exact magnitude of burn injuries among children in this region. Hence a retrospective observational study is designed to get a data for this region.

Objectives are to study the profile of burn cases treated at Jubilee Mission Medical College Hospital in children below 12 years; to find out the mode and manner of infliction of burn injury and to study the distribution and outcome.

#### MATERIALS AND METHODS

It was a retrospective observational study. Medical records of patients with the diagnosis of acute burns admitted to Jubilee Mission Medical College Hospital during 01-07-2016 to 30-06-2017 (one year) were reviewed. All cases of burns among children below the age of 12 years were included whereas burns cases above the age of 12 years were excluded.

**Data collection and analysis:** The patient's data were collected in a pre-structured proforma. Data collected were age, gender, mode of infliction, manner of infliction, distribution of burns and final outcome. Standard Lund and Browder charts as appropriate for patient age were used for rapid assessment of Total Body Surface Area (TBSA) involved. Data were analysed using Microsoft excel and results were presented with frequency and percentage and illustrated with charts and tables.

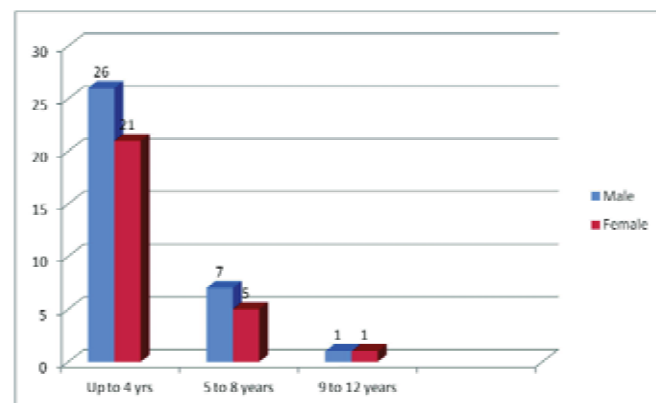


**Figure 1** Distribution of cases

#### RESULTS

A total of 169 burn cases were treated in Jubilee Mission Medical College Hospital, Thrissur during the study period. Out of 169 cases, 61 (36.09%) were children below 12 years as shown in **Figure 1**.

Among the 61 cases, 35 (57.38%) were male children and 26 (42.62%) were female children. The children were categorized in to three groups (up to 4 years, 5 to 8 years and 9 to 12 years) and the number of cases in each group is shown in **Figure 2**.



**Figure 2** Age wise distribution of cases

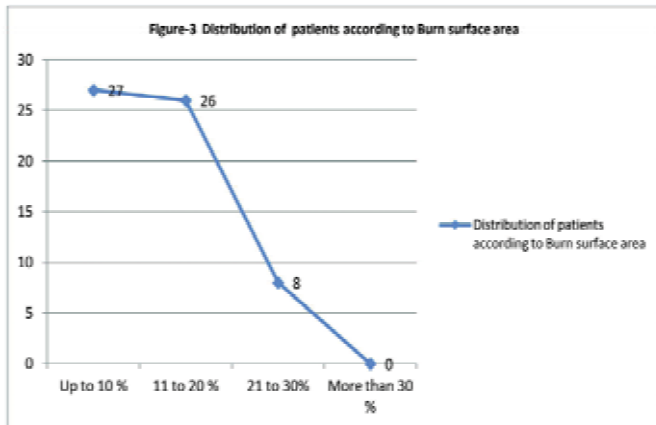
**Table 1** Source of burns in accidental cases

Source of burn	No: of cases	Percentage
Spillage of boiled water	25	41.67
Spillage of hot beverages	15	25.00
Crackers	5	08.33
Burning of clothes	4	06.67
Fall in to hot water	4	06.67
Hot Cooking oil	3	05.00
Dipping of hands in hot water	3	05.00
Contact with hot tar	1	01.66
	60	100.00

**Table 1** depicts manner and source of burns. Out of the 61 cases, the manner of burns was accidental in nature in 60 cases. Scalding was the predominant cause of injuries and the source of burns in alleged accidental cases is shown in Only one case was reported as homicidal in which the father set ablaze a 12 year old female child.

All the ten victims of flame burns were male children and they were above the age group of 5 years.

Assessment of Total Body Surface Area (TBSA) involved was calculated and the patients were categorized in to four groups. The number of patients in each category is shown in **Figure 3**.



**Figure 3** Distribution of patients according to burns surface area

## DISCUSSION

The frequency of representation of children among burns victims admitted to hospital and their sex distribution in our study was similar to previous reports from elsewhere.<sup>5</sup> Male children are at increased risk; may be because of their greater activity levels, risk taking behaviours and fire play. Predominance of lower age group children observed in our study was similar with another report which states that in India children in the age group of 0 to 5 years account for 50% of all childhood burns.<sup>6</sup> Another study says that nearly a fourth of all burn injuries occur in children under the age of 16 years, of whom the majority are below the age of 5 years.<sup>7</sup> Observation of scalding being the predominant cause of injury in this group was consistent with the Indore study<sup>8</sup> which showed similar findings. This is in contrast from African study which reported that flame burns accounted for 57% and scalding only in 32% cases of childhood burns.<sup>9</sup>

All the ten victims of flame burns in our study were male children and they were above the age group of 5 years. This shows that younger children are more likely to sustain injuries from scalded burns that are caused by hot liquids or kitchen preparations while older children are prone for injuries from flame burns. Playing with matches and cigarette lighter, bursting of crackers were the main causes of flame burns in this study.

In the present study one case was a homicide in which the father poured kerosene on his 12 year old daughter and tried to burn. She escaped with 12% total body burn surface area. The reason was familial disharmony. Other than this no cases of child abuse was reported in our study. But to bring the child abuse cases to the light a careful investigation is required especially by a team comprising experts from fields of medicine, psychology, social work and law. In an analysis of paediatric burns admissions to a hospital in India during the years 1992-2007,<sup>4</sup> 9.3% of burn injuries were found to be secondary to abuse. According to another study, burns account for 10% of all cases of child abuse and majority of victims are less than 2 years of age where scalding is the most common cause.<sup>10</sup>

Among the study group 26 cases suffered from burns with less than 10% total body surface area and 27 cases suffered from 11 to 20% burns. No cases were reported with more than 30% burns and mortality was not reported. Mortality rate is nearly 100% only if the burns are affected with more than 40% total body surface area.<sup>11</sup>

## Key Preventive Tips

Use safe cooking practices such as never leaving food unattended on stove. Supervise or restrict children from using of utensils with cooked food or boiled water or beverages. A water heater with pre-set at lower temperature in home will be a safe guard; possible in high income group families. Recognize burn hazards like children playing around open flames, unattended hot liquids, unattended heaters and traditional stoves. Impart community Education programmes focusing on reduction of such hazards, modification of environment like stable raised cooking surfaces and barriers to separate play and cooking areas.

## CONCLUSION

Burns are preventable. Mortality and morbidity due to burns in developed countries is in a lower rate due to prevention strategies and improvement in care of burn cases. But in developing countries burn injury in children continues to be a major epidemiological problem. An intense campaign to make people aware of risk factors and their avoidance is required to reduce the number of burn accidents in children. It is also essential to encourage the development of burn care systems including training the health care providers in managing people with burns.

**Limitation of the study:** Within all countries burn risk correlates with socioeconomic status and it was reported that people living in low and middle-income groups are at a higher risk for burns than people living high income groups. However, socio economic factors were not taken in to consideration in this study.

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## ORIGINAL PAPER

# A study of hypertension and its risk factors among females of reproductive age group

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### ABSTRACT

**Background:** The prevalence of hypertension has increased over the last decade. The lifetime risk of becoming hypertensive in industrialized countries was estimated to exceed 90%. **Objectives:** To assess the association of hypertension and its risk factors among female of reproductive age group of Guwahati, Assam. **Materials and methods:** The present study is a cross-sectional study carried out in urban areas of Guwahati city among women of reproductive age group. Among the study population of 100, a predesigned and pre-tested interview schedule was used to record the socio-demographic and risk factors of hypertension, height, weight and blood pressure of participants. Descriptive and inferential statistics was used to find out the association of hypertension with the selected risk factors. **Results:** The percentage of pre-hypertensive was 60%, stage- 1 hypertensive was 24, and stage-2 hypertensive was 2%. There was a significant association of hypertension with overweight, physical activity, socio-economic status, and intake of extra-salt in diet. **Conclusion:** The prevention and control of hypertension is a major concern because it is a major modifiable risk factor for coronary artery diseases and stroke. It is also necessary to control the B.P as early as possible to prevent end organ damage. The warning remains stark. The problem already extends far beyond the capacity of the developing countries to cope.

**Keywords:** BMI; socio-economic status; physical activity.

### INTRODUCTION

Hypertension contributes to the burden of heart disease, stroke and kidney failure and premature mortality and disability. It disproportionately affects populations in low- and middle-income countries where health systems are weak. Hypertension rarely causes symptoms in the early stages and

many people go undiagnosed. Those who are diagnosed may not have access to treatment and may not be able to successfully control their illness over the long term. There are significant health and economic gains attached to early detection, adequate treatment and good control of hypertension. Treating the complications of hypertension entails costly interventions such as cardiac bypass surgery, carotid artery surgery and dialysis, draining individual and government budgets. Addressing behavioral risk factors, e.g., unhealthy diet, harmful use of alcohol and physical inactivity, can prevent hypertension. Tobacco use increases the risk of complications of hypertension. If no action is taken to reduce exposure to these factors, cardiovascular disease incidence, including hypertension, will increase. Salt reduction initiatives can make a major contribution to prevention and control of high blood pressure.<sup>1</sup>

The Global Burden of Disease study has reported HTN as the 4th contributor to premature death in developed countries and the 7th in the developing countries.<sup>2</sup> Analysis of worldwide data on global burden of HTN showed an overall prevalence of 26.4% among the adult population in 2000.<sup>3</sup> In India, the prevalence of HTN ranges between 20%–40% in urban areas and 12%–17% among rural adults.<sup>4</sup>

Raised blood pressure is estimated to cause 7.5 million deaths,

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about 12.8% of all deaths. It is a major risk factor for cardiovascular disease. The prevalence of raised blood pressure is similar across all income groups, though it is generally lowest in high-income populations.<sup>5</sup> The rise of NCDs among younger populations may jeopardize many countries “demographic dividend,” including the economic benefits expected to be generated during the period when a relatively larger part of the population is of working age. Instead, these countries will have to contend with the costs associated with populations that are living with longer episodes of ill health. A growing number of young adults are being affected, prompting the conclusion that the country could lose the next generation to chronic disease.<sup>6</sup> Attempts to “treat the way out” of NCDs will not be affordable for most middle- and low-income countries. Action should be oriented toward curbing the NCD risk factors and promoting healthier lifestyles to reduce NCD incidence rates and push back the age of NCD onset.<sup>7</sup>

Assam being culturally diverse state differences may be noted in different communities which may be attributable to their differences in their habits. The purpose of this study is to identify the major risk factors for hypertension. As the disease burden has also shifted from the older age group to the more productive middle age group. The study has been carried out among the females of reproductive age group.

This paper has aimed to assess the prevalence of hypertension and its risk factors among female of reproductive age group of Guwahati, Assam.

## MATERIALS AND METHODS

The study is a descriptive cross-sectional study carried out in selected urban areas of Guwahati city, Assam. 100 women in the age group of 20-49 years of age who are not taking

anti-hypertensive drugs and who are not actually ill were selected by random sampling methods. Pregnant and lactating mother up to the age of 12 weeks were excluded from the study.

A semi structured interview schedule was used to collect information from the subjects such as socio-demographic data, risk factors. Blood pressure for each participant was measured as per AHA guidelines.<sup>8</sup> Classification of hypertension was done based on JNC VII criteria.<sup>9</sup> Clients BMI was calculated by using the formulae  $Wt (kg) / Ht (m^2)$ , i.e., Quetelet's index. W.H.O Asian BMI classification was used to classify women according to their BMI<sup>10</sup> Descriptive and inferential statistics was used to find out the association of hypertension with the selected risk factors. Selected variables are age, occupation, socio-economic status, caste, socio-economic status, obesity, physical activity, dietary pattern, intake of extra salt in diet.  $P < 0.05$  was taken as significant.

## RESULTS

In the study population, 40% are in the age group of 20-29, 48% participants are in the age group of 30 to 39 years and 12% are in the age group of 40-49. The percentage of pre-hypertensive was 60%, stage -1 hypertension was 24% and stage-2 hypertension was 2% respectively. 52% are having their BMI in the normal range and 36% are overweight and 12% are obese. Majority (90%) of participants were Hindu. 42% of participants were either graduates or post-graduates. 94% of the participants are unemployed. Based on Kuppuswamy's socioeconomic status scale majority (92%) of the participants are from upper middle class. 50% are having their BMI in the normal range and 36% are overweight and 12% are obese.

**Table 1** Mean blood pressure level according to age, prevalence of hypertension and isolated systolic hypertension (n=100)

Age Group In years	Frequency	Mean	SD	Hypertensive Cases	Isolated systolic hypertensive cases	
					Stage-1	Stage-2
20-29	40	118.800	10.787	6	2	0
30-39	48	125.416	14.440	18	6	2
40-49	12	125.000	7.974	2	2	0

**Table 2** Physical activity (as measured by IPAQ) and hypertension n=100

HIN	Level of Physical Activity			Total	Chi Sq.	df
	High	Low	Medium			
Normal	6	2	6	14	25.185	4
Pre-hypertensive	4	6	50	60		
Hypertensive	2	10	14	26		
Total	12	18	70	100		

$$\chi^2 = 13.277 \text{ at } df = 4, p < 0.01$$

There is significant association of level of physical activity as measured by International Physical Activity Questionnaire

and hypertension as measured by sphygmomanometer among women of reproductive age group of Guwahati at 0.01 level of significance.

**Table 3** Association of selected factors and hypertension  $n=100$

SL No	Selected Factors:	Hypertensive	Non-hypertensive	Total	Chi square Value
1	<b>Age in years</b>				3.610
	Up to 30 years	10	38	48	
	>30 years	16	26	52	
	<b>Total</b>	26	74	100	
2	<b>Occupation</b>				0.003
	Housewife	24	70	94	
	Working lady	2	4	6	
	<b>TOTAL</b>	26	74	100	
3	<b>Family History</b>				4.082
	<b>Present</b>	6	6	12	
	<b>Absent</b>	20	68	88	
	<b>Total</b>	26	74	100	
4	<b>BMI&lt;30</b>	22	66	88	0.071
	<b>BMI&gt;=30</b>	4	8	12	
	<b>Total</b>	26	74	100	
5	<b>Uses extra salt</b>	20	20	40	19.958
	<b>Does not use extra salt</b>	6	54	60	
	<b>Total</b>	26	74	100	
6	<b>Vegetarian</b>	10	58	68	14.088
	<b>Non-vegetarian</b>	16	16	32	
	<b>Total</b>	26	74	100	

$$\chi^2 = 3.841 \text{ at } df = 1, p < 0.05, 2 = 6.635 \text{ at } df = 1, p < 0.01$$

There is significant association of presence of family history of hypertension and hypertension as measured by sphygmomanometer among women of reproductive age group of Guwahati at 0.05 level of significance.

There is significant association of use of extra salt in meals and hypertension as measured by sphygmomanometer among women of reproductive age group of Guwahati at 0.01 level of significance.

There is also significant association of dietary pattern (vegetarian or non-vegetarian) and hypertension as measured

by sphygmomanometer among women of reproductive age group of Guwahati at 0.01 level of significance.

## DISCUSSION

The Indian health system is challenged with major non-communicable diseases and hypertension is the major among them. The study was carried out in urban areas of Guwahati. This is comparable with the findings of the study conducted by Madhumitha M et al 2014.<sup>11</sup> Prevalence of hypertension was found to be 37.6% in Raichur district of North Karnataka. Prevalence of hypertension was significantly associated with



smoking, fruits and vegetables intake, salt intake, junk foods, family history of hypertension and obesity. There is no significant association between prevalence of hypertension and type of diet (vegetarian or non-vegetarian), alcohol intake and physical activity.<sup>11</sup>

As per the study done by NK Bansal & N Goswami 2014, the prevalence of pre-hypertension was found to be 32.41% (n=294) among 18-35 years UG and PG students in Guwahati. A significantly higher prevalence of pre-hypertension was found in individuals with increasing age (p=0.008), family history of hypertension (p<0.00001), overweight/obesity (p<0.00001), central obesity (p<0.001) and physical inactivity (p<0.001). The most prevalent risk factor among the pre-hypertensive individuals was family history of hypertension (70.4%), followed by overweight/obesity (65.6%), central obesity (51%) and physical inactivity (27.6%).<sup>12</sup>

According to this study, significant association was seen between hypertension and level of physical activity, presence of family history of hypertension, use of extra salt and dietary pattern of women of reproductive age group of Guwahati city. The percentage of pre-hypertensive was 60%, stage -1 hypertension was 24% and stage-2 hypertension was 2% respectively in the present study.

Over all prevalence of hypertension among tea garden workers of Assam was 60.8%. There were more women with hypertension i.e., 62.2% than men i.e. 59.4% although this difference was not statistically significant.<sup>13</sup> The overall prevalence of hypertension in native rural population of Assam was 33.3% i.e., 33.2% in male and 33.4% in female.<sup>14</sup>

### Conclusion and recommendation

Hypertension is a growing problem among the women of reproductive age group with pre-hypertensive 60%, stage -1 hypertension 24% and stage-2 hypertension 2% respectively in the present study. Use of extra salt in the diet, non-vegetarian diet, decreased physical activity and having family history of hypertension are the major risk factors of hypertension among women of reproductive age group of Assam.

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## ORIGINAL PAPER

# Patient's satisfaction with nursing care at tertiary care centre

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### ABSTRACT

**Introduction:** Patient's satisfaction has become increasingly popular, as a critical component in the measurement of nursing skill. **Objectives:** To assess the level of patient satisfaction with nursing care and its association with various demographic variables. **Materials and methods:** This descriptive study design with over 64 patients at tertiary care centre was done by using a pre-text, pre-designed proforma. **Result:** Quite a good number of patients, i.e., 72% has showed their moderate satisfaction with the ways that nursing professional undertake. **Conclusion:** Nursing care is a key determinant of overall patient satisfaction during hospital admission. The nurses need to know what factors influence patient satisfaction, if we have to improve the quality of health care.

**Keywords:** Government hospital; duration of hospitalization.

### INTRODUCTION

Patient's satisfaction is one of the outcomes for healthcare delivery system. It is measured with a long history in the social science.<sup>1</sup> Nursing professionals are the frontline caregiver that patients most likely to confront with, spend the highest amount of time with and rely upon for recovery during their hospital stay. Nursing care plays a prominent role in determining the overall satisfaction of patient's hospitalization experience.<sup>2</sup>

Patient satisfaction is a term that can be interpreted differently by patients; its meaning can also differ for the same patient at different times.<sup>3,4</sup> Patient satisfaction has been defined as the patients perception of care received compared with the care expected.<sup>5</sup> Aiello et al concluded that patients base their expectations on their encounters with behaviors of nurses.<sup>6</sup> Bowling indicated that there is prevalent recognition in health

policy of the significance of evaluating health services from patients perspectives and that patients evaluation of their healthcare are now an established component of quality assessment, mainly through surveys of patient satisfaction.<sup>7</sup>

Assessing patient satisfaction with nursing care is important in evaluating whether patient's needs are fulfilled and subsequently facilitating in the planning as well as implementing appropriate nursing interventions for patients. Determining factors that contribute most to patient satisfaction can further assist nurses in improving the quality of nursing care. Hence, patient satisfaction with nursing care is an imperative determinant of quality of care particularly in the clinical/ healthcare facility settings.<sup>2</sup>

Patients in the general wards needs prolonged hospital stay. Prolonged hospital stay itself can cause Hospital Acquired Infection (HAI), psychological stress and other complications. So nursing professionals should focus on a comprehensive care to the patient in order to satisfy their stay during the period of hospitalization.<sup>8</sup>

### MATERIALS AND METHODS

This prospective and descriptive study design was carried

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out on 64 patients admitted in the Gauhati Medical College and Hospital, Guwahati, Assam during the year 2018. Human institutional ethical clearance was obtained prior to collection of the data.

A pre-text, pre-designed proforma (satisfaction rating scale) was used with a structured interview schedule. Data thus collected were analyzed by using SPSS software-18.

## RESULTS

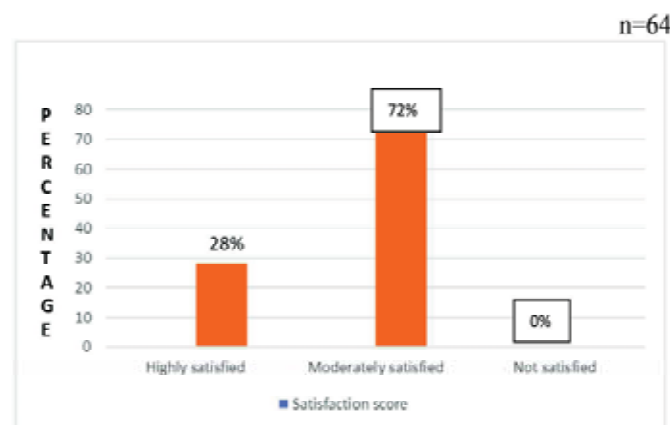
100 in-patient were approached out of which only 64 patients responded to our study, so response rate was 64%. The data were grouped and analysed under the following sections:

### Section I: Frequency and Percentage distribution of participants according to Demographic characteristics.

Out of a total of 100 in-patients, 64 respondents successfully completed the study. Majority of patients, i.e., 16(25%) belonged to 31-40 age group, 45(70%) respondents were male, 50(78%) were married, 24(38%) respondents are illiterate, 28(44%) were farmers, 25(39%) had a family income of Rs 2,096- Rs 6,213. 38(59%) of respondents belonged to upper class of Socioeconomic status (modified BJ Prasad scale 2015), 45(70%) resided in rural area, 50 (78%) are Hindu by religion.

37(58%) respondents were suffering from surgical ailment, rest medical ailments. 34(53%) did not have previous history of hospitalization. Of the remaining 30(46%) who had previous history of hospitalization, 22(73%) were admitted in government hospital, 17(77%) of who were under tertiary health care. 42(66%) respondent were partially dependent on nursing care and 38(59%) were having hospital stay for more than 7 days.

### Section II Patient satisfaction with nursing care



**Figure 1** Distribution of patient satisfaction score with nursing care

The data presented in **Figure 1** depicts that out of 64 patients, 18(28%) are highly satisfied and the rest, i.e., 46(72%) were moderately satisfied.

### Section III: Association of satisfaction score with demographic variables

The study showed that there is a significant association

between satisfaction score and selected demographic variables, i.e., marital status and previous history of hospitalization at 0.05 level of significance.

**Age:** The calculated value was 3.59 and the tabulated value was 18.31. Since calculated value was less than tabulated value there was no significant association between satisfaction and age.

**Sex:** The calculated value was 5.70 and the tabulated value was 5.99. Since calculated value was less than tabulated value there was no significant association between satisfaction and sex.

**Marital status:** The calculated value was 17.6 and the tabulated value was 12.59. Since calculated value was more than tabulated value there was significant association between satisfaction and marital status.

**Educational status:** The calculated value was 9.8 and the tabulated value was 26.30. Since calculated value was less than tabulated value there was no significant association between satisfaction and educational status.

**Type of ailment patient is suffering from:** The calculated value was 1.84 and the tabulated value was 5.99. Since calculated value was less than tabulated value there was no significant association between satisfaction and type of ailment patient is suffering from.

**Occupation:** The calculated value was 3.87 and the tabulated value was 15.5. Since calculated value was less than tabulated value there was no significant association between satisfaction and occupation.

**Total family income:** The calculated value was 4.04 and the tabulated value was 21.03. Since calculated value was less than tabulated value there was no significant association between satisfaction and total family income.

**Socioeconomic status:** The calculated value was 8.76 and the tabulated value was 15.51. Since calculated value was less than tabulated value there was no significant association between satisfaction and socioeconomic status.

**Residence of the patient:** The calculated value was 0.61 and the tabulated value was 9.49. Since calculated value was less than tabulated value there was no significant association between satisfaction and residence.

**Religion:** The calculated value was 0.39 and the tabulated value was 12.59. Since calculated value was less than tabulated value there was no significant association between satisfaction and religion.

**Previous history of hospitalization:** The calculated value was 7.02 and the tabulated value was 5.99. Since calculated value was more than tabulated value there was significant association between satisfaction and previous history of hospitalization.

**Dependency of the patient on nursing care:** The calculated value was 6.61 and the tabulated value was 9.49. Since calculated value was less than tabulated value there was no significant association between satisfaction and dependency



of the patient on nursing care.

**Duration of hospital stay:** The calculated value was 1.08 and the tabulated value was 9.49. Since calculated value was less than tabulated value there was no significant association between satisfaction and duration of hospital stay.

## DISCUSSIONS

The present study reveals majority of patients 46(72%) were moderately satisfied, 18(28%) were highly satisfied and none of them had poor satisfaction. The study findings were consistent with the studies done by Lindgren et al, nursing care.<sup>9</sup>

The study findings shows that married patients and history of previously hospitalized patients are benefitted more than other variables. Hence the hypotheses  $H_1$  stated that there is a significant association between the level of satisfaction of nursing care among patients and their selected demographic variables was accepted at  $p < 0.05$ .

This study findings were consistent with the studies done by Konduru A et al.<sup>10</sup>

## CONCLUSIONS

Patient's views have become an important element in the evaluation of health care. The nurses need to know what factors influence patient satisfaction, if we have to improve the quality of health care. Deficits in hospital care quality were common in all countries. Improvement of hospital work environment might be a relatively low cost strategy to improve the quality in hospital care and to increase patient satisfaction.

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**Declaration:** All the author declare that: (1) The article is original with the author(s) and does not infringe any copyright or violate any other right of any third party. (2) The article has not been published (whole or in part) elsewhere, and is not being considered for publication elsewhere in any form, except as provided herein. (3) All author(s) have contributed sufficiently in the article to take public responsibility for it and (4) all author(s) have reviewed the final version of the above manuscript and approved it for publication. The contributions were made as: Nabajani Dutta: Concept, design,

data collection, manuscript writing; Prof. Putul Mahanta: Study design and interpretation of data; Dr. Kahua Das: Concept, design and draft writing.

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ORIGINAL PAPER

# Cardiac dysfunction in diabetes mellitus: a hospital based study

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## ABSTRACT

**Introduction:** Diabetic Cardiomyopathy is characterized by the presence of myocardial dysfunction in the absence of hypertension, coronary artery disease, or other known cardiac disease. **Materials and methods:** It was a hospital based observational, descriptive study carried out in 105 diabetic patients who were screened for cardiac dysfunction using 2D echocardiography. **Results:** Left ventricular diastolic dysfunction (grade 1) was found in 69 patients of the study population. Out of 69, 10 patients (9.5%) had left ventricular diastolic dysfunction in the absence of hypertension, coronary artery disease or other known cardiac disease. **Conclusion:** 9.5% of 105 diabetic patients studied had presence of left ventricular diastolic dysfunction in the absence of hypertension, coronary artery disease or other known cardiac disease. These patients may be considered to be having Diabetic Cardiomyopathy.

**Keywords:** Diastolic dysfunction; cardiomyopathy; hypertension; coronary artery disease.

## INTRODUCTION

The American Diabetes Association has rightly designated diabetes mellitus as “coronary heart disease equivalent” as it is associated with a number of cardiovascular complications namely atherosclerotic coronary artery disease, myocardial infarction, congestive heart failure, coronary microangiopathy and systemic arterial hypertension.<sup>1</sup> In addition to these, structural myocardial involvement termed as “Diabetic cardiomyopathy” may occur, which has been suggested by various studies done on diabetics till date.<sup>2</sup> These conditions are rarely found as isolated forms; they often overlap and potentiate each other. Diabetes mellitus can lead to heart failure, not only by augmenting the impact of cardiovascular risk factors, but also via the direct deleterious effect on the

myocardium per se which is known as Diabetic Cardiomyopathy.<sup>2</sup>

Diabetic Cardiomyopathy is characterized by the presence of myocardial dysfunction in the absence of hypertension, coronary artery disease, or other known cardiac disease.<sup>3</sup> The prevalence of diabetic cardiomyopathy in diabetic patients is 12% and reaches 22% in individuals over 64 years.<sup>4</sup> Although it commonly affects the diastolic and systolic function of the left ventricle, there are scanty data indicating that diabetes is equally detrimental for the right ventricle as well.<sup>2</sup>

The Diabetic Cardiomyopathy is a diagnosis of suspicion. Unfortunately, there is no widely accepted method for its diagnosis.<sup>5</sup> The best approach is detection of myocardial dysfunction, and exclusion of other heart diseases, which may cause myocardial structural and functional changes. Clinically, it may take several years for heart failure to develop in diabetic patients. So, it is essential to demonstrate the abnormality before symptoms of heart failure begin. Echocardiography is a reliable and non-invasive imaging tool which can be used to demonstrate early functional changes of left ventricle. However, normal echocardiographic findings at rest do not exclude the diagnosis of diabetic Cardiomyopathy.<sup>5</sup> Left ventricular dysfunction detected by

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Tissue Doppler Imaging (TDI), during exercise or stress, may be the earliest sign of diabetic Cardiomyopathy. Other diagnostic methods such as Computed Tomography (CT), single photon emission CT, and Magnetic Resonance Imaging (MRI) may be used for detection of myocardial dysfunction. Assessment of interstitial fibrosis and steatosis by using delayed Gadolinium enhancement cardiac MRI is possible, but its diagnostic value has not been established.<sup>5</sup>

Very few studies have been done to find out the prevalence of cardiomyopathy in Diabetes Mellitus in Indian population. The present study is an attempt to identify echocardiographic evidence of cardiac dysfunction in Diabetes Mellitus in the absence of hypertension, coronary artery disease and other known cardiac diseases.

### MATERIALS AND METHODS

This was a hospital based observational, descriptive study carried out in patients attending the outpatient department of Medicine and Emergency department in Gauhati Medical College and Hospital, Guwahati during a period of one year. Patients above 18 years of age and belonging to either sex who were already on drugs for diabetes mellitus and/or fulfilling the diagnostic criteria of Diabetes mellitus as per the American Diabetes Association were included in the study. Patients aged less than 18 years and above 60 years, patients with chronic renal disease, microalbuminuria, chronic pulmonary disease, chronic liver disease, congestive cardiac failure, anabolic steroid users, patients with a history of alcohol consumption, chemotherapeutic agents or radiotherapy, collagen vascular disease and endocrinopathy (excluding diabetes mellitus), congenital and valvular heart diseases, neuromuscular disorders, family history of cardiomyopathy and pregnant patients were excluded from the study.

A scheme of case taking or proforma was filled up meticulously for every patient included in the study by interviewing patients/attendants, thorough clinical examination and relevant investigations. The evidence for the presence of coronary artery disease was obtained through history regarding coronary ischemic events, ECG (q wave, right bundle branch block, left axis deviation) and ECHO findings including past medical records and coronary angiography (in some). Echocardiography was done using the SIEMENS ACUSON CV70. Operators blinded to the diagnosis of diabetes in the study population performed all echocardiographic measurements. The presence of diastolic and systolic dysfunction, left ventricular hypertrophy and regional wall motion abnormality was looked for.

### RESULTS

105 diabetic patients were included in this study, out of which 73 were males and 32 were females. 11 patients belonged to the age-group of 31-40 years, 38 to 41-50 years and 56 belonged to 51-60 years age-group. Systemic hypertension was present in 42 patients and coronary artery disease was present in 40 patients. **Table 1** shows the distribution of diastolic dysfunction in the study population.

**Table 1** Distribution of cases with diastolic dysfunction in the total study population

Diastolic dysfunction	Number of patients (n=105)	Percentage (%)
Present	69	65.7
Absent	36	34.3

Diastolic dysfunction was detected in 69 out of 105 patients. In 59 patients out of these 69, hypertension and / or coronary artery disease was present, and in 10 patients diastolic dysfunction was present in absence of either of these. **Table 2** shows distribution of diastolic dysfunction in the study population in absence of hypertension and coronary artery disease.

**Table 2** Distribution of cases with diastolic dysfunction in the absence of hypertension and coronary artery disease

Diastolic dysfunction	Number of patients (n=105)	Percentage (%)
With HTN/ CAD/both	59	56
Without any of the above	10	9.5
No Diastolic dysfunction	36	34.5

Out of these 10 patients who had diastolic dysfunction in absence of hypertension and coronary artery disease, majority (6 out of 10) belonged to the age group of 51 to 60 years (**Table 3**).

**Table 3** Age-wise distribution of patients with diastolic dysfunction without hypertension and coronary artery disease

Age group	Number (n=10)	Percentage (%)
31-40	0	0
41-50	4	40
51-60	6	60

### DISCUSSION

In the present study, out of 105 diabetic patients, 73(69.5%) were males and 32(30.5%) were females. Maximum number of patients was in the age-group 51-60 years (53.4%). 42 patients (40%) were hypertensive, while coronary artery disease was present in 40 patients (38%).

2D- echocardiography was performed on all patients and diastolic dysfunction of grade-1 was present in 69(65.7%). Dikshit NM et al, performed a cross-sectional study in 2013 on 50 asymptomatic diabetics and found diastolic dysfunction in 66% of diabetics.<sup>6</sup> Patil MB et al performed a cross-sectional hospital based study in 2012 in 50 patients with asymptomatic type 2 diabetes mellitus and found diastolic dysfunction in 64% of study population.<sup>7</sup> Moreover, studies conducted by Poulsen MK et al which demonstrated that



there exists an association between type 2 diabetes mellitus and heart failure with preserved ejection fraction, the prevalence of abnormal diastolic dysfunction had been reported to be 43-75%.<sup>8</sup> Poirier et al found left ventricular diastolic dysfunction in 60% of subjects with diabetes mellitus.<sup>9</sup>

In our study, 10 patients out of the study population of 105 cases had evidence of diastolic dysfunction on echocardiography in the absence of hypertension, coronary artery disease and other known cardiac diseases. The incidence of diastolic dysfunction in patients of diabetes mellitus in the absence of hypertension, coronary artery disease and other known cardiac diseases are reported by several other workers. Dandamudi S et al in a cross-sectional study involving diabetic patients, found that 16.9% patients had diastolic dysfunction on echocardiography in the absence of evidence of other cardiac disease.<sup>10</sup> Trachanas K et al reported the prevalence of Diabetic Cardiomyopathy to be 12%.<sup>2</sup> Dhar R et al in their prospective study on 100 newly diagnosed type 2 diabetes mellitus aged between 30-60 years found that 39% of the patients had developed diabetic cardiomyopathy.<sup>11</sup> Chaudhary AK et al conducted a cross-sectional study on 100 newly diagnosed normotensive patients of type 2 diabetes mellitus aged 30-60 years of age and found that diabetic cardiomyopathy was found in 41% of the study population.<sup>12</sup> Thus the prevalence of Diabetic Cardiomyopathy was found to vary in different studies. In our study, the incidence of Diabetic Cardiomyopathy was found to be 9.5%.

In our study, among 10 patients with diastolic dysfunction without CAD and hypertension, majority (60%) patients belonged to the age-group 51-60 years. Londhe A. et al in their study on 200 normotensive type 2 diabetics without cardiovascular involvement, observed that 57.14% patients belonged to the 50-59 years age-group.<sup>13</sup>

## CONCLUSION

It is well known that diabetes is capable of producing myocardial dysfunction independent of coronary artery disease, hypertension and other known cardiac disease. This entity has been named as Diabetic Cardiomyopathy, the existence of which has been a subject of controversy.

Several studies have been carried out to find the exact prevalence of this condition among diabetics with variable results. In our study, the incidence of left ventricular diastolic dysfunction in the study population comprising of 105 diabetic patients in absence of hypertension, coronary artery disease or other known cardiac disease was found to be 9.5%. Although small in number, this group of patients falls into the category of Diabetic Cardiomyopathy. However, prospective studies with larger sample sizes are necessary to arrive at a definite conclusion.

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## ORIGINAL PAPER

# A clinical study of neurological disorders in peripartum period

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## ABSTRACT

**Background:** Identification and treatment of neurological disorders in women during the peripartum period presents a special challenge to the neurologist and other health providers since this state can precipitate a myriad of new neurologic and psychiatric symptoms. The lack of knowledge is due to the fact that research on pregnant woman is technically difficult, challenging & highly regulated due to ethical concerns. **Objectives:** This study was planned to study the clinical profile of various neurological disorders seen during the peripartum period. **Materials and methods:** This prospective observational study was carried out among 34,302 pregnant patients of age  $\geq 16$  yrs presenting to our department (or OPD) of Neurology or Department of Obstetrics and Gynaecology (or OPD) between October 2011 to November 2013. **Results:** A total of 200 patients presented during pregnancy or puerperium with neurological disorders during the study period. 50.5% of the cases were diagnosed with eclampsia, followed by AIDP in 24.5% cases. Maximum number of patients presented with convulsion (67%), followed by altered sensorium (59.0%). Among 24 patients with stroke, the number of patients with non-hemorrhagic and hemorrhagic stroke was 16(66.66%) and 8(33.34%) respectively. **Conclusion:** We found multi axial involvement and broad range of neurological disorders in the peripartum period with eclampsia and stroke topping the list. The incidence of AIDP was significantly high, the establishment of cause of which needs further studies.

**Keywords:** Acute Inflammatory Demyelinating Polyradiculoneuropathy; convulsions; eclampsia; migraine; stroke.

## INTRODUCTION

The range of neurological conditions affecting woman of reproductive age is extremely broad.<sup>1-2</sup> The state of pregnancy and puerperium heralds enormous and rapid women experience rapid physiological changes precipitating new neurologic or psychiatric symptoms. The humongous adaptations and modifications in neuronatomy reproductive

endocrinology, systemic & cerebral circulation and coagulation profile and metabolism can predispose to the onset or deterioration of various neurological disorders. The lack of knowledge is due to the fact that research on pregnant woman is technically difficult, challenging & highly regulated due to ethical concerns. Various neurological conditions commonly seen in pregnant women and puerperium are Epilepsy, Eclampsia, Cerebrovascular disorders, peripheral neuropathy (Acute Inflammatory Demyelinating Polyradiculoneuropathy, AIDP), Intra Cerebral Hemorrhage (ICH) & Cerebral Venous Thrombosis (CVT) among others. Certain disorders are found to be more common in peripartum period which includes last 10% of gestational period, i.e., last 1 month of gestation up to few weeks after delivery with references to the mother. There are very few studies in our country to know the extent of this problem. With this background in mind we planned to undertake this study.

This paper has aimed to study the clinical profile of various neurological disorders seen during peripartum period and to investigate the etiological factors of it.

## MATERIALS AND METHODS

This is a prospective observational study conducted in the department of Neurology, GMCH, Guwahati during the period from October 2011 to November 2013. Cases were selected of age  $\geq 16$  yrs presenting to the Department of Neurology or Department of Obstetrics and Gynaecology or attending the Neurology, Obstetrics OPDs using stringent inclusion and exclusion criteria with the approval of ethical committee.

**Statistical analysis** were performed using the Microsoft

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Excel program, 2007 edition and the GraphPad INSTAT4 program. In the course of the evaluation of the data gathered, descriptive statistical methods (average, standard deviation) were used. The results of these tests were considered at the significance level of  $p < 0.05$  and the confidence interval 95%.

## RESULTS

A total of 200 patients presented during pregnancy or puerperium with neurological disorders during the study period between October 2011 to November 2013. The total number of deliveries in this period in this hospital was 34,302, giving an incidence of 583.06 per 1, 00,000 of deliveries. The mean age was  $24.06 \pm 4.913$  (95% CI:23.379- 24.741), of which 160(80%) were primigravida and rest 40(20%) were multigravida.

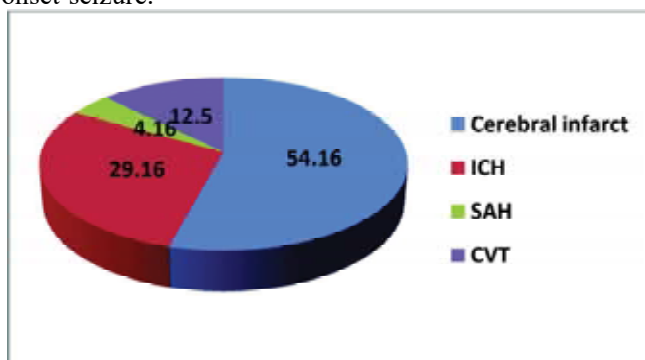
**Table 1** Showing the demographic data of the study population

Parameter	Value
Age (yr) Mean $\pm$ SD	$24.06 \pm 4.913$
95% CI	23.379- 24.741
Range	16-40
ParityPrimigravida (total no with % in bracket)	160 (80.0)
Multigravida ( total no with % in bracket)	40 (20.0)

## Spectrum of Neurological Disorders in Peripartum Women:

Two hundred patients presented with new onset peripartum neurological disorders. Eclampsia was diagnosed in 101 out of 200 patients (50.5%). The incidence of eclampsia was 294.44 per 1,00,000 deliveries.

Maximum number of patients presented with convulsion (67%), followed by altered sensorium (59.0%). 30% patients had some degree of muscular weakness and 23% patients presented with symptoms suggestive of cranial nerve involvement e.g. inability to swallow, pooling of saliva, facial deviation etc. The most common presenting symptom was seizure. 134 out of 200 patients (67%) presented with new onset seizure.



**Figure 1** Types of stroke seen in peripartum period

(ICH : Intracerebral Hemorrhage. SAH : Subarachnoid Hemorrhage. CVT : Cerebral venous thrombosis)

**Table 2** Spectrum of neurological disorders during peripartum period

Neurological disorder	Number of cases	Percentage	Incidence per 1,00,000 deliveries
Eclampsia	101	50.5	294.44
AIDP	49	24.5	142.85
Stroke	24	12.00	69.96
Tubercular Meningitis (TBM)	4	2	11.66
Spinal Cord Pathology	3	1.5	8.74
Metabolic Encephalopathy due to Dyselectrolytemia	3	1.5	8.74
Migraine	2	1	5.83
Prolapsed Intervertebral Disc Lesion (PIVD)	2	1	5.83
Encephalomyelitis	2	1	5.83
Bell's palsy	2	1	5.83
Septic Encephalopathy	2	1	5.83
Cerebellar ataxia	1	0.5	2.91
Space Occupying Lesion(SOL)	1	0.5	2.91
Sensory neuropathy	1	0.5	2.91
Altered sensorium of undetermined origin	3	1.5	8.74

## Presenting symptoms:

**Table 3** Presenting symptoms of neurological disorders in peripartum period

Presenting symptom	No of cases	Percentage
Altered consciousness	118	59.0
Convulsion	134	67.0
Muscular weakness	60	30
Symptoms suggestive of cranial nerve involvement	46	23
Sensory abnormality	13	6.5
Fever	7	3.5
Nausea/vomiting	4	2
Headache	11	5.5
Abnormal movement	1	0.5

Types of strokes seen in peripartum period were cerebral infarct (54.16%), ICH(29.16%) ,CVT(12.5%) and SAH(4.16%).

**Table 4** Etiology of non-hemorrhagic stroke in peripartum period

Non hemorrhagic stroke (16 nos)	
Cause	No of cases
CVT	3
Leukaemia	1
Postpartum angiopathy	1
Undetermined	11

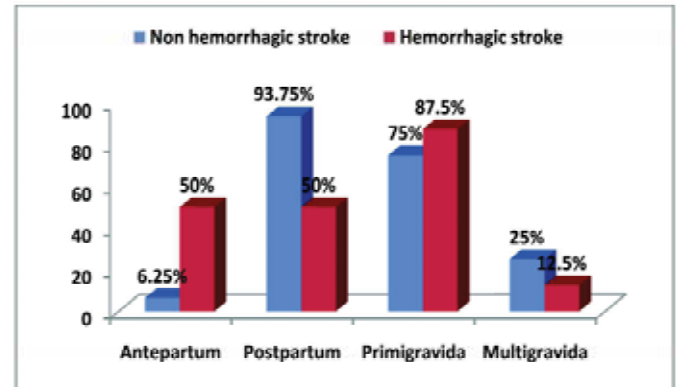
**Table 5** Etiology of hemorrhagic stroke in peripartum period

Hemorrhagic stroke (8 nos)			
Intra-cerebral hemorrhage		Subarachnoid hemorrhage	
Cause	No of cases	Cause	No of cases
AVM	1	Undetermined cause of SAH	1
Undetermined	6		

Among 24 patients with stroke, the number of patients with non-hemorrhagic and hemorrhagic stroke was 16(66.66%) and 8(33.34%) respectively. Postpartum angiopathy was seen in only one patient who had no previous history of hypertension.

## DISCUSSION

We observed an incidence of new onset neurological disorders of 583.06 per 1,00,000 deliveries, which is similar



**Figure 2** Comparison of timing and parity of the patients with hemorrhagic and non-hemorrhagic stroke

to a study by Gupta S et al,<sup>3</sup> who reported an incidence of 584 per 1,00,000 deliveries. However, Gupta S et al<sup>3</sup> in their study excluded patients with eclampsia but included patients with pre-existing neurological disorders. By retrospectively examining the database of 10 years in a hospital at Hong Kong, To WK et al,<sup>4</sup> reported the incidence of neurological disorder as 326 per 1,00,000 pregnancies. Thus the reported incidence varies significantly across different studies. Since the inclusion and exclusion criteria varies among these studies, the study population across these studies are not comparable. The distribution of incidence of eclampsia varies across the globe. Europe, USA and eastern parts of Asia enjoy a low incidence whereas it is high in India. The mean age with SD of patients presenting with new onset neurological disorder in our study was  $24.06 \pm 4.913$ , 80.0% of them were primigravida and 20% were multigravida. 60.5% of these patients presented in their postpartum period. We could not gather any information regarding these parameters in various studies even after a careful search of literature.

### *Spectrum of neurological disorders in peripartum women:*

In our study the highest number of patients were diagnosed with eclampsia (50.5%) followed by AIDP (24.5%), Stroke (12.00%) and other less prevalent disorders.

Eclampsia is defined as seizures in a woman with preeclampsia that cannot be attributed to any other cause.<sup>5</sup> In our study, the incidence of eclampsia was 294.44 per 1,00,000 deliveries. The mean age with SD was  $23.356 \pm 4.78$  years, 84.16% were primigravida and 57.43% presented during postpartum period. This is in sync with a study by Al-hayali et al<sup>6</sup>, who reported a mean age with SD of their patient population as  $23.47 \pm 5.32$  years with 85% primigravida and 60% presented during antepartum period. Although many studies carried out in India have excluded eclampsia from their patient population.<sup>3,5,7,8</sup>, the one reported by Singh S et al<sup>9</sup> estimates the incidence to be 3.2%, 82.27% were primigravida and 18.4% presented during postpartum period. To WK et al<sup>4</sup> reported an incidence of 39 per 1,00,000 pregnancies but no data regarding the parity status or timing of presentation was shown. The mean age and parity status of eclamptic



patients in our study correlates well with the studies by Singh S et al<sup>9</sup> and Al-Hayali RM et al.<sup>6</sup> But in these two studies maximum patients presented during antepartum period, whereas we observed maximum incidence during postpartum period. Neuroimaging revealed features suggestive of hypertensive encephalopathy/Posterior Reversible Encephalopathic Syndrome (PRES) and cerebral oedema in all patients with eclampsia.

### Stroke

In our study the incidence of stroke was found to be 69.96 per 1,00,000 deliveries. Our observation correlates with that of Jaigobin C et al (69%).<sup>10</sup> Whereas Sharshar T et al<sup>11</sup> reported a lower incidence of 8.9%. Both the study by us and Jaigobin et al<sup>10</sup> are studies carried out in single tertiary care hospital, whereas the study by Sharshar T et al<sup>11</sup> was carried out in 63 public maternities. As some studies examining the incidence of stroke in peripartum period is population-based whereas some others are single-hospital based studies, it is difficult to arrive at a consensus regarding the exact incidence. The percentage of patients with stroke in our study was 12%, and it correlates with that of Gupta S et al (11.9%).<sup>3</sup> But the incidence that is reported in studies by Janaki et al (49.5%),<sup>7</sup> Agarwal K (82.7%)<sup>8</sup> and Srinivasan K et al (60.3%)<sup>5</sup> is higher than in this study. It may be because of the less cases of CVT (1.5% in our study and 6.6% in study by Gupta S et al<sup>3</sup>) as compared to these studies where CVT accounted for 35–65% of the cases. Regarding the timing of pregnancy associated stroke, different studies provide conflicting results. It has been recently reported that the risk is greatest during the postpartum period.<sup>10</sup> In our study most patients presented in the postpartum period (79.17%). It has been suggested that large reduction of blood volume following delivery, hormonal changes, hypercoagulability of pregnancy state, dehydration, anaemia following child delivery increases the incidence of stroke in the postpartum period.

In prior studies, only in a small proportion of patients an etiologic diagnosis of stroke could be reached.<sup>10</sup> The proportion of patients during peripartum period presenting with non-hemorrhagic stroke is frequently reported to be more than those presenting with hemorrhagic stroke.<sup>3,10</sup> In our study 66.66% presented with non-hemorrhagic stroke. Whereas, Sharshar T et al<sup>11</sup> reported that the percentage of patients with hemorrhagic and non-hemorrhagic stroke is equal, it is assumed that the majority of strokes associated with pregnancy are secondary to venous thrombosis.<sup>12</sup> Two recent studies by Kalita J et al<sup>13</sup> and Narayan D et al<sup>12</sup> from India identified peripartum period as a risk factor for CVT. In our study, all the 3 patients with CVT were confirmed with appropriate neuroimaging technique and they presented during postpartum period. In the present study due to socio cultural reason, less number of patients had CVT. In other parts of India a pregnant women is subjected to restrictions in relation to food and movement. This however is not practised in Assam.

### AIDP

49 out of 200 patients were diagnosed with AIDP, the incidence being 142.85 per 1,00,000 deliveries. It is generally regarded that the incidence of Guillain –Barre Syndrome (GBS) during pregnancy is similar to that of general population.<sup>14</sup> Chan LY et al<sup>15</sup> mentioning the work of Alter M et al,<sup>16</sup> reported that incidence of GBS range from 0.6 to 4.0/1,00,000 population. Compared to these data, the incidence in our study is alarmingly high. Though the exact reason behind it is not known to us and should be investigated, postpartum flairs are common due to delayed hypersensitivity, immunization, acute infection and surgical procedure.<sup>17</sup> In our study, 71.42% presented during postpartum period. Chan LY et al<sup>15</sup> also observed increased incidence during postpartum period with a rate ratio of 2.93(95% CI 1.20–7.11) during the first 30 days after delivery. Primigravida accounted for 75.5% patients with AIDP.

In our study, 5 patients (10.20%) needed mechanical ventilatory support while 6.12% of patients died. This is in contrast to an earlier study by Nelson LH et al<sup>18</sup> that as many as 34.5% of women suffering from GBS during pregnancy required ventilatory support and the maternal mortality exceeded 10%. Out of 24 patients who followed up during the study period, 18 patients had complete recovery and 6 patients had residual weakness at 6 months and remaining are not in follow up.

In our study, 2% patients presented with TBM, in contrast to that reported by Gupta S et al,<sup>3</sup> (15.8%), whereas other study done by Janaki S et al.<sup>7</sup> Agarwal K et al,<sup>8</sup> Srinivasan K et al,<sup>5</sup> reported low percentages of CNS infection (4.1%, 5.7%, 4.4% respectively). All these studies included broader term “CNS infection”, without mention of specific etiology. So incidence of TBM is not comparable to our study. Neurological diseases may be incidental to pregnancy (e.g., meningitis), usually presenting with classical manifestations. It commonly occurs between the 5<sup>th</sup> and 7<sup>th</sup> months or in the postpartum period. Most patients improve with treatment (Gupta S et al).<sup>3</sup> Our patients with TBM, mostly presented during post partum period and responded to treatment.

In our study, spinal cord pathology was found in 3(1.5%) patients, similar to Gupta S et al<sup>3</sup> (1.5%) and in contrast to Srinivasan S et al<sup>5</sup> (7.4%). Our study is the first in India to report occurrence of cerebellar ataxia (0.5%). One patient had hyperemesis gravidarum, leading to nutritional deficiency and she responded well to injectable preparation of multivitamins.

1(0.5%) patient was diagnosed with pretectal space occupying lesion with hydrocephalus. Prior to this pregnancy she was asymptomatic. Agarwal et al<sup>8</sup> and Gupta S et al<sup>3</sup> observed that 1.1% and 1.3% patients presented with SOL respectively. To WK et al,<sup>4</sup> Janaki et al<sup>7</sup> and Srinivasan et al<sup>5</sup> reported higher percentage (7.5%, 7.2% and 23.5% respectively). Usually there is an increase in the size of the tumour during pregnancy due to hormonal changes and amelioration of symptoms in the postpartum period.

We got 2(1%) cases of Bell's palsy, one in postpartum period and one in the third trimester. Rosenbaum RB et al,<sup>19</sup> reported that the incidence of Bell's palsy is higher during pregnancy and the puerperium (38–45 women per 1,00,000 pregnancies v 17 per 1,00,000 women-years in non-pregnant women of childbearing age). In our study, 2(1%) patients presented with migraine without any antecedent history prior to this pregnancy. Goadsby PJ et al<sup>20</sup> showed that migraine is 3 times more common in women (3:1 ratio) and female headache prevalence is highest during childbearing years. However, studies by Goadsby PJ et al,<sup>20</sup> Sances G et al<sup>21</sup> have shown that the incidence of migraine headache is often reduced during the second 2 trimesters of pregnancy but in our study our patients presented in term pregnancy only.

## CONCLUSION

Neurological disorders are an important cause of mortality and morbidity in reproductive age group. We found multi axial involvement and broad range of neurological disorders in the peripartum period. The most common new onset neurological disorder was Eclampsia followed by AIDP and Stroke. Eclampsia was the most common cause of new onset seizure in the peripartum period followed by stroke. In our study, the incidence of AIDP was very high as compared to other studies. The exact reasons of which needs further investigations.

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ORIGINAL PAPER

# Bacterial infections in cirrhosis of liver: a hospital based study

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## ABSTRACT

**Introduction:** Bacterial infections represents one of the most important precipitating event for acute decompensation and mortality in a case of cirrhosis of liver. Patients with cirrhosis are highly susceptible for bacterial infections and their severe courses. Infections occur more often in advanced stage of liver disease, impair hepatic function, trigger the onset of complications, and are significant factors of mortality as well. Gastrointestinal hemorrhage confers a higher risk for infections and infections play important role in provoking of variceal bleeding episodes and can also be associated with the failure to control bleeding. The incidence and severity of infection in cirrhosis is greater than in the population without cirrhosis. Infection with multi resistant organisms is common in cirrhosis and its occurrence is associated with higher mortality rates than in patients without cirrhosis. The end-organ damaging effect of bacterial infection is greater in patients with cirrhosis due to altered sensitivity, which often culminates in acute-on-chronic liver failure. Delays in the diagnosis and start of treatment results in higher mortality particularly in hypotensive patients with cirrhosis. **Materials and methods:** This was a hospital based observational, descriptive study to find data on bacterial infection in 123 cirrhotic patients. **Results:** Bacterial infection was present in 41(33.33%) patients of study population. SBP was the most common (39.02%) bacterial infection documented. In hospital mortality was highest with Child Pugh Class C (50%). **Conclusion:** With increase in Child Pugh Class, bacterial infections and in hospital mortality increases.

**Keywords:** Child pugh score; culture isolates; in hospital mortality.

## INTRODUCTION

Cirrhosis of Liver is considered as an immunocompromised state that leads to a variety of infections which then accounts

for an approximately 30% mortality.<sup>1</sup> Bacterial infections occur in 32% to 34% of admitted patients with cirrhosis<sup>2</sup> and in 45% of those with gastrointestinal hemorrhage.<sup>3</sup>

In cirrhosis, bacterial infection is defined as a pathological process caused by invasion of normally sterile tissue, fluid or cavity by pathogenic or potentially pathogenic bacteria. Approximately one-third of bacterial infections are community acquired, one-third health care associated and one-third nosocomial.<sup>4</sup>

Infections are increasingly recognized as a major trigger of systemic inflammation and organ failure in advanced cirrhosis leading to a fourfold increased mortality.<sup>5</sup>

Decompensated liver cirrhosis predisposes to delayed intestinal transit time, increased intestinal permeability and disturbed expression of intestinal antimicrobial peptides thereby facilitating the translocation of bacteria and bacterial products from the gastrointestinal lumen through the lamina propria into the mesenteric lymph nodes, ascitic fluid and systemic circulation.<sup>6</sup> Gram negative enteric bacilli translocate more easily than gram positive bacteria and obligate anaerobes.<sup>7</sup>

The most common bacterial infections encountered in clinical practice in cirrhosis are spontaneous bacterial peritonitis (25%-31%), urinary tract infections (20%-25%), pneumonia

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(15%-21%), and soft tissue infections (11%).<sup>8</sup>

Infection leads to accelerated deterioration of liver function and is the most common identifiable extra hepatic trigger of acute-on-chronic liver failure (ACLF), which is characterized by organ failure and extremely poor survival (28-day mortality rate 30–40%).<sup>9</sup> Systemic inflammation triggered by infection may cause ACLF through complex mechanisms including an exaggerated inflammatory response and systemic oxidative stress via pathogen-or danger/damage-associated molecular patterns and/or alteration of tissue homeostasis as a consequence of inflammation. These features may induce tissue damage (cell dysfunction, apoptosis, or necrosis), organ failure, and even death. Thus, understanding characteristics of infection in patients with ACLF is important.

## MATERIALS AND METHODS

This was a hospital based observational, descriptive study carried out in Department of Medicine, in Gauhati Medical College and Hospital, Guwahati during a period of one year. Patients above 12 years of age and belonging to either sex who were cirrhotic were included in the study. Patients aged less than 12 years, not willing to give consent and patients on antibiotic therapy during admission were excluded from the study. A scheme of case taking or proforma was filled up meticulously for every patient included in the study by interviewing patients/attendants, thorough clinical examination and relevant investigations.

The case of clinical cirrhosis of the liver will be defined as a patient having at least one clinical sign of hepato cellular failure and one of the portal hypertension along with at least three USG findings suggestive of cirrhosis of liver.<sup>10,11</sup>

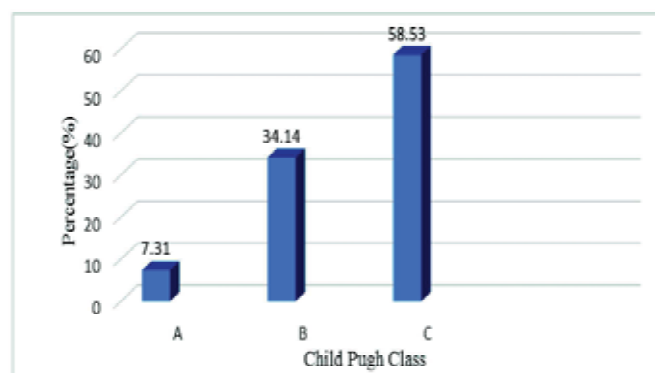
The diagnosis of Spontaneous Bacterial Peritonitis (SBP) was made by >250 neutrocytes in ascitic fluid and/or positive culture for a certain germ and exclusion of other secondary causes of peritonitis. Urinary Tract Infection (UTI) diagnosis was made by clinical symptoms and signs (dysuria, fever), >10 leucocytes in urinalysis and/or positive blood culture (>10,000 CFU/ml). The diagnosis of Respiratory Tract Infection (RTI) was made by clinical symptoms and signs (fever, cough, expectoration, pulmonary sound); positive radiological signs (patchy alveolar opacities); and/or positive bacteriological examination (sputum). Skin and soft tissue infections (SSTI) were diagnosed by fever, local signs (blush, tumefaction and pain), leukocytosis with neutrophilia, positive cultures of wound secretions.<sup>12,13</sup>

Statistical analysis was done with Windows Excel 2013 and Graph Pad prism 7.02. Fischer's Exact Test was used to calculate p value.

## RESULTS

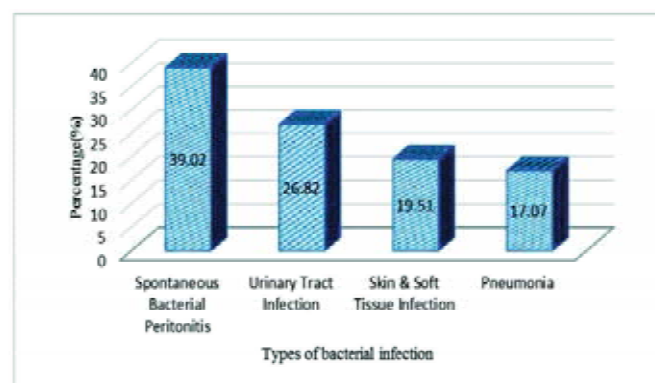
Out of 123 cirrhotic patients, 41 (33.33%) had bacterial infection. Apart from upper GI bleeding, patients without infections 82 (66.66%) were admitted due to other reasons like uncomplicated ascites, various stages of hepatic encephalopathy, electrolyte imbalance and hepatoma. Total number of male patients were 92 (74.79%) and 31 (25.20%)

were female patients. Maximum number of patients in the study group were between 55–64 years of age (34.95%). The most common cause of cirrhosis was alcohol (79.67%) followed by Cryptogenic, Hepatitis B, Hepatitis C, Hepatitis B + Alcohol and Hepatitis C + Alcohol. Majority of the study population belonged to Child Pugh Class C (58.3%) (Figure 1).



**Figure 1** Distribution of Child Pugh Class

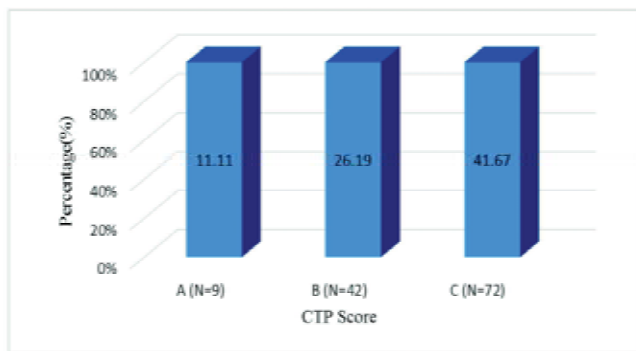
The most common type of infection in the study group was Spontaneous Bacterial Peritonitis (36.58%) followed by Urinary Tract Infection (26.82%), Skin and soft tissue infection (19.51%) and Pneumonia (17.07%) (Figure 2).



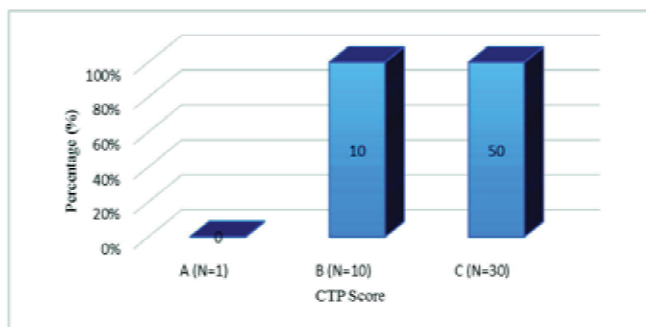
**Figure 2** Frequency of Infection Types

Ascitic fluid culture was positive in 26.67% of cases. E coli was the most common (20%) bacterial isolate followed by Klebsiella (6.67%). Urine culture was positive in 81.82% of cases with E coli being the most common (54.54%) bacterial isolate followed by Enterococcus (18.18%) and Klebsiella (9.09%). Culture positivity in cases of pneumonia were 71.32% with Streptococcus pneumonia being the most common bacterial isolate (57.14%) followed by Klebsiella pneumonia (14.28%). Culture were positive in 37.5% cases of skin and soft tissue infection. Most common bacterial isolate from swab culture was Staphylococcus aureus in 25% cases followed by E coli in 12.5%. Frequency of bacterial infection (41.67%) (Figure 3) and in hospital mortality (30%) (Figure 4) were significantly ( $p < 0.05$ ) higher in Child Pugh Class C than Child Pugh Class A-B.



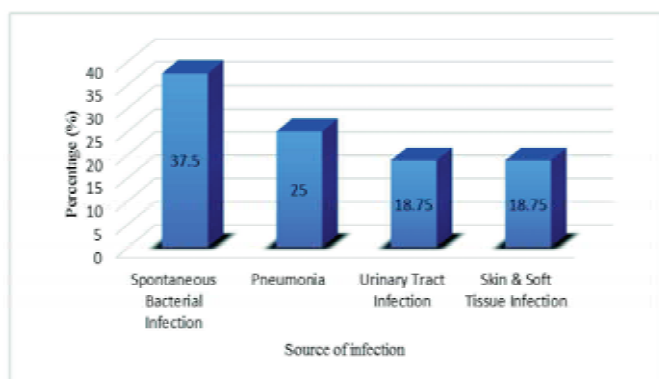


**Figure 3** Bacterial Infection in relation to CTP



**Figure 4** Hospital Mortality in patients with bacterial infection

In hospital mortality was seen highest with Spontaneous Bacterial Peritonitis (37.5%) followed by Pneumoniae (25%). Both UTI and Skin & Soft Tissue Infection were associated with in hospital mortality in 18.75% of cases (**Figure 5**).



**Figure 5** Hospital Mortality in relation to source of infection

## DISCUSSION

In the current study the mean age of presentation was 53.5 years and males constituted the majority of the cases 74.79%. In a meta analysis conducted by Aravanti et al in 2010, mean age of bacterial infection in cirrhotic patients was 56 years and majority of them were males 68.3%.<sup>14</sup>

In the present study, alcohol was identified as the commonest cause of cirrhosis in 79.67% cases followed by cryptogenic in 12.19%; Hepatitis B in 4.06% and Hepatitis C in 1.62%

cases. Karki et al in 2014 reported 84% alcoholic cirrhosis 12% Hepatitis C related and 8.2% Hepatitis B related.<sup>15</sup> In the current study upper GI bleed was present in 34.95% of the patients which is comparable with findings of Park et al 2015 where upper Gastro-intestinal bleed in alcoholic cirrhosis with bacterial infection was reported in 33.8% cases.<sup>16</sup>

In our study 33.33% of patients were found to have bacterial infections which was comparable with Fernandez et al 2012 study that reported 25% to 35% patients develop bacterial infection in cirrhosis at the time of admission or after hospitalization.<sup>17</sup> In the present study SBP was reported as the most common type of bacterial infection in patients with cirrhosis, 39.02%. Ascitic Fluid culture was positive in 26.65% of cases with E-coli being the most common bacterial isolate. Purohit 2015 has reported 43.80% cases of SBP in patients with cirrhosis where culture positive cases were 43.6% with E-coli as the most common isolate.<sup>18</sup> The low proportion of positive Ascitic fluid culture in our study is probably due to the relatively low concentration of bacteria in Ascitic fluid.

UTI was the second most common bacterial infection in the current study is 26.82% with 81.81% of the cases being culture positive where E coli was the most common isolate from urine. Lee et al in 2015 reported that in cirrhotic patients 80% of UTI is culture positive with the large majority being gram negative bacilli (76%) and E coli being the commonest.<sup>19</sup>

In the present study frequency of pneumonia was 17.07% with 71.32% culture positive cases. Streptococcus pneumonia was isolated in 57. 145 cases and Klebsiella pneumonia from 14.28% cases. Fernandez et al in 2002 reported 15% cases of pneumonia in their study.<sup>20</sup> Sunil K et al in 2011 found 70% sputum culture positive cases in cirrhotics.<sup>12</sup> Gustot et al 2012 also reported that the most common bacterial isolate was Streptococcus pneumonia in cirrhotic patients with pneumonia.<sup>21</sup>

In our study skin and soft tissue infection was present in 19.51% of cases. Most common bacterial isolate was Staphylococcus aureus 25% followed by E coli 12.25%. Mohan et al in 2010 showed the prevalence of cellulitis in cirrhotic between 10.5%- 12.5% with E coli as the commonest isolate.<sup>22</sup> Hamaza et al in 2014 also reported Klebsiella, Pseudomonas, Staphylococcus and E coli as common bacterial isolates from cellulitis in cirrhosis.<sup>23</sup>

In the present study in-hospital mortality was seen mostly with Child Pugh Class C i.e., 50%. With Child Pugh Class B mortality was 10%. No mortality was seen with Child Pugh Class A. Maximum mortality was seen with SBP 37.50% followed by Pneumoniae 25% and UTI and SSTI both 18.75%. Our study is comparable to study by Scott et al 2013 where worsening liver disease correlated with increased mortality: 3.1% Class A, 23.6% Class B and 32.8% Class C.<sup>24</sup> Bal et al in 2016 in-hospital mortality rates attributable to SBP 43.11%.<sup>25</sup> Tsao et al in 2004 reported mortality for first episode of SBP ranges from 10% to 25%.<sup>26</sup> Ghaliony et al in 2015 reported mortality of 15% in cirrhotics with pneumonia.<sup>27</sup>

Fernandez et al in 2012 reported in-hospital mortality between 10% to 18% in Cirrhotics with UTI.<sup>28</sup> Mortality of 19% was seen in cirrhotics with SSTI as reported by Mohan et al in 2011.<sup>22</sup> Probably the higher rates of mortality in the present study may be due to lack of proper health care facilities and patients presenting late in decompensated stages.

## CONCLUSION

Cirrhosis of liver is a condition with varied manifestations. Unfortunately, in this part of the country, patient presents with advanced stage of the disease. Alcohol is the most common etiological factor for cirrhosis followed by cryptogenic with ascites being the most common presentation. As cirrhosis is considered as an immunocompromised state it leads to a variety of infections. The most common bacterial infection in patients of cirrhosis in order of frequency is spontaneous bacterial peritonitis followed by urinary tract infection, skin and soft tissue infection and pneumonia. Most common bacterial isolates from spontaneous bacterial peritonitis and urinary tract infection was gram negative bacilli whereas gram positive cocci was the most common isolate in cases of pneumonia and skin and soft tissue infection. In hospital mortality and distribution of bacterial infection in Child Pugh Class C was significantly higher ( $p < 0.0285$ ) than Child Pugh Class A-B. Bacterial infection most frequently associated with in hospital mortality is Spontaneous Bacterial Peritonitis. Although small in number, this group of patients falls into the category of Bacterial Infection in Cirrhosis. However, prospective studies with larger sample sizes are necessary to arrive at a definite conclusion.

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**Ethical clearance:** Taken.

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## ORIGINAL PAPER

# Profile of victims examined under POCSO Act 2012, in JNIMS, Imphal

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### ABSTRACT

**Background:** Sexual assault on women and children is one of the most heinous crimes. Now with civilisation going forward, sexual crime against children has gone up and a serious understanding on ways to prevent and cope with it is the need of the hour for a better society. **Materials and methods:** The study was conducted in JNIMS, Imphal, from 1<sup>st</sup> August, 2015 to 31<sup>st</sup> July, 2018 in which 80 victims of sexual assault cases were brought for medico legal examination. **Results:** The most vulnerable age group was 14-17 years (60%). 85% of the victims were students. The commonest place of assault was the house of relatives of accuse (32.5%). In 96.2% of cases, the act was committed by known persons. The natures of occurrence of sexual relationship in 46.3% cases were of elopement. Maximum (35%) cases were medico-legally examined between 72 hrs to 1 week of incidents. Hymen was found torn with old tears in 59.5% cases. **Conclusion:** The study shows that young girls of 14-17 years are more vulnerable to sexual assault. So, a need to spread awareness among parents and children on sexual crimes and the benefit of early reporting and medical examination is required, as delay causes loss of evidences.

**Keywords:** Sexual assault victims; vulnerable age group; consent, hymen.

### INTRODUCTION

According to NCRB data 2016 the incidents of sexual assault cases in children shows a constantly rising pattern with low conviction rate.<sup>1</sup> Stringent laws are made to prevent children from sexual exploitation, but despite this, cases have been reported and is increasing in magnitude. These cases are only the tip of the iceberg and many cases go unreported. Sexual violence is ubiquitous, it occurs in every culture, in all levels of society and in every country of the world.<sup>2</sup> Sexual assault

causes tremendous physical and psychological trauma in women and children. The WHO reports in 2002 that 150 million girls and 70 million boys under 18 years experience some forms of sexual violence globally.<sup>3</sup>

In India, as per 2011 census, there are 472 million children under the age of 18 years, who constitute 39% of the total population.<sup>4</sup> Every second child is being exposed to one or the other form of sexual abuse and every fifth child faces critical form of it.<sup>5</sup>

To deal with child sexual abuse cases, the Government of India passed a special law, “The Protection of Children from Sexual Offences(POCSO) Act, 2012.” This act is a comprehensive law to provide for the protection of children from the offences of sexual assault, sexual harassment and pornography, while safeguarding the interest of the child at every stage of the judicial process.<sup>6</sup>

This paper has aimed to study the profile of sexual assault victims under POCSO Act, 2012 and to study the incidence and the medico-legal aspects of the same.

### MATERIALS AND METHODS

The study was conducted in the department of Forensic Medicine and Toxicology, Jawaharlal Nehru Institute of Medical Sciences, Imphal, Manipur, India. It is a retrospective study based on cases of alleged sexual assaults registered under POCSO Act, 2012, received for examination during

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the period from 1<sup>st</sup> August, 2015 to 31<sup>st</sup> July, 2018. The data was retrieved from the police requisition letter, medico-legal certificates, history revealed by the victims during examination. Profile of victims examined under POCSO Act 2012.

The details pertaining to socio-demographic factors, season, place of incidence, relationship of the victims with accused, time interval between alleged incidents and medical examinations, and conditions of hymen were entered on a self-designed proforma. The data were statistically analyzed and discussed.

## RESULTS

In the present study, 80 cases of sexual assault under POCSO Act were examined during the years 2015 to 2018. All victims were female. The age of the victim ranged from 2 yrs to 18 yrs. The most vulnerable age group was 14-17 yrs (60%) followed by 10-13 yrs (23.8%), 6-9 yrs (8.8%). Religion of most of the victims were Hindus (68.7%) and majority of the victims belong to the Meitei community (66.2%). All the victims were unmarried and 66(82.5%) cases come from rural areas. 68(85%) victims of sexual assault cases were students, followed by school drop-outs in 7(8.8%) cases (Table 1).

**Table 1** Socio demographic profile of sexual assault victims

Category	Number	Percentage (%)
<b>Age</b>		
2-5 yrs	6	7.5
6-9 yrs	7	8.8
10-13 yrs	19	23.7
14-17 yrs	48	60.0
Total	80	100.0
<b>Region</b>		
Urban	14	17.5
Rural	66	82.5
Total	80	100
<b>Literacy</b>		
Pre-school	2	2.5
Illiterate	3	3.7
Students	68	85
School dropout	7	8.8
Total	80	100

Only few cases of sexual assaults occurred in the morning, majority of the cases (52.5%) occurred in between 12 pm to 6 pm. Most assaults were reported in summer season (33.7%) followed by spring (31.3%) and least was in autumn (13.7%) (Table 2).

The commonest place of assault was the house of the accuses relatives in 26(32.5%) cases followed by the house of accused in 19(23.8%) cases and victim's house in 11(13.8%) (Table 3). In 77(96.2%) cases, the act was committed by known persons, while in 3(3.8%) cases the assailants were strangers. Majority of the alleged accused were boyfriends in 43(53.7%) cases, followed by neighbours in 18(22.5%) (Table 3). The

nature of occurrence of sexual relationship in 37(46.3%) of the cases were of elopement.

**Table 2** Sexual assaults according to time and season

Category	Number	Percentage (%)
<b>Time</b>		
12.00am to 6.00am	2	2.5
6.00am to 12.00pm	16	20.0
12.00pm to 6.00pm	42	52.5
6.00pm to 12.00am	20	25.0
Total	80	100.0
<b>Season</b>		
Spring (Mar-Jun)	25	31.3
Summer (Jun-Aug)	27	33.7
Autumn (Sep-Nov)	11	13.7
Winter (Dec-Feb)	17	21.3
Total	80	100.0

**Table 3** Place of incidents and relationship of victims to accused

Category	Number	Percentage (%)
<b>Place of incidents</b>		
Relative/acquaintance	26	32.5
Accuses' house	19	23.8
Field	9	11.2
Neighbour's house	5	6.2
Hotel / restaurant	7	8.8
Victim's house	11	13.8
Others	3	3.7
Total	80	100.0
<b>Relationship</b>		
Boyfriend	43	53.7
Parent	1	1.2
Guardian	5	6.3
Relative	5	6.3
Neighbour	18	22.5
Friend / known	5	6.3
Stranger	3	3.7
Total	80	100.0

28(35%) cases were medico-legally examined between 72 hrs to 1 week of incidence followed by 19(23.7%) between 1 week to 1 month, 17(21.35%) in more than 1 month. Only 7(8.7%) cases were examined on the same day of incident (Table 4).

**Table 4** Time interval between alleged incidence and medical examination

Time interval	Frequency	Percentage (%)
<=24 hrs	7	8.7
24 hrs – 48 hrs	3	3.8
48 hrs – 72 hrs	6	7.5
72 hrs – 1 week	28	35.0
1 week – 1 month	19	23.7
>1 month	17	21.3
Total	80	100.0

Evaluation of the mental status of the victim at the time of examination showed 98.7% as calm. It was further observed that external injuries on the body were found in only 1.3% of case and local injuries were seen in 3.8%. Hymen was found torn with old tears in 47(59.5%), intact in 25(31.6%) and torn with fresh tears in 7( 8.9%) (**Table 5**).

**Table 5** Distribution of victims according to injuries found on the body

Injury	Number	Percentage (%)
<b>External injury</b>		
Absent	78	98.7
Present	1	1.3
Total	79	100
<b>Local injury</b>		
Absent	76	96.2
Present	3	3.8
Total	79	100

## DISCUSSION

Studies conducted throughout the world showed that sexual assault cases are increasing in both children and adolescents.<sup>7,8</sup> Girls are more vulnerable to sexual abuse, although boys too reported a high percentage of victimization and are subjected to greater social stigma.<sup>9</sup> In our study, all victims were females. Similar findings were seen in a study done by Maring et al.<sup>10</sup> and Sarkar SC et al.<sup>11</sup> where female child victim (98.7%) outnumbered their male counterparts (1.3%).

Our study revealed that the most vulnerable age group was 14-17 yrs in 48(60%) cases followed by 10-13 yrs in 19(23.7%) cases. This is in agreement with studies of Surender et al.<sup>12</sup> Who reported 48.06% victims in the age group of 16-18 yrs followed by 11-15 yrs in 33.7% and Kaushik et al.<sup>13</sup> Who revealed 45.16% victims in the age group of 14-17 yrs. Similar findings were noticed by Sharma et al.<sup>14</sup> In our study majority of the alleged victims consented for sex. This shows lack of awareness about the legal age of sexual consent for both genders.

In our study most of the victims were Hindus 55(68.7%) followed by Muslims in 21(26.3%) and Christian in 4(5.0%) cases only. The findings are in agreement with study of Yadav et al.<sup>15</sup> and Surender et al.<sup>12</sup> This can be explained by the fact that Hindus predominates in most of the areas under study. In previous study done in the state by Maring et al.<sup>10</sup> majority of the victims were Meitei is followed by Manipuri Muslims. This is consistent with the findings of the present study and this may be due to dominance of the local population in Manipur by the Meiteis. Higher incidence of sexual assault was observed in rural area (82.5%) as compare to urban area (17.5%). This could be due to lack of entertainment and recreational facilities and urbanization in rural areas. This finding is consistent with a study by Bijoy TH et al.<sup>16</sup> In our study, most of the victims were students 68(85%). Similar

findings were made by Surender et al.<sup>12</sup> who reported that 71.2% were students. The reason being most of the children go to school at this age group.

Most of the cases of sexual assault occurred in between 12 pm to 6 pm. This is in contrast to the findings by Sujatha et al.<sup>17</sup> where most incidents occurred in between 6 pm to 12 am. Maximum number of the incidents occurred during summer accounting for 33.7% followed by Spring 25 (31.3%). Similar findings were observed by Bijoy TH et al.<sup>16</sup> Further, this may be explained by children getting to know each other during festive seasons (Spring) and getting eloped during summer vacation. However, Surrender et al.<sup>12</sup> reported that maximum cases occurred during winter. This may be explained by geographical and seasonal variations in various parts of the world.

In our study most of the sexual assaults (56.3%) occurred in the house of the accused or his relative and acquaintance house. These findings are in consistent with the studies of Surender et al.<sup>12</sup> and Arif M et al.<sup>18</sup> who reported that 38.67% and 57.89% of cases occurred in accuses' house respectively. This may be due to the fact that most parents go to work during this time of the day and children are left alone at home.

Significant relationship was noted between the victim and accused in our study as the offence occurred in a familiar setting. In this study most of the sexual assaults were committed by known assailants constituting 96.2% and only 3.8% were committed by strangers. Many authors have reported similar findings.<sup>10,12,16,18</sup> Relationship of some kind or other may have convinced the victims for commission of the offence. In our study, 43(53.7%) of the accused were boyfriends and 18(22.5%) were neighbours. This is consistent with the study made by Surender et al.<sup>12</sup> who reported that 26.5% of assailants were neighbour. Reasons being most of the cases were consented act and later complaints were lodged when there was refusal to marry by the male partner.

In the present study, the natures of offence in 37(46.3%) cases were of elopement where victims consented for the act. They were brought under POCSO Act on complaints of their parents. It was observed that maximum number 28(35%) of cases were examined between 72 hrs to 1 week of assault followed by 19(23.7%) after a week to month and 17(21.3%) after 1 month. In a study by Surender et al.<sup>12</sup> 24.8% victims were examined in third day to a week and 18.23% after a week to month, which is in accordance with our study. In our study, only 7(8.7%) were examined within 24 hrs of the incidence which is consistent with the studies made by Sarkar et al.<sup>11</sup> and Sujatha et al.<sup>17</sup> who observed that 10% and 8.5% victims were examined on the day of assault respectively. Late reporting in this study may be due to indecisiveness on the part of the victim, fear of insult and social stigma that would be face by the victim and family and in some cases victim eloped with accused to some other distant places.

Out of 80 cases, 79 consented for physical examination, out of which only 1(1.3%) case had external injury on the body while majority of cases 78(98.7%) had no injury. It was also

observed that only 3(3.8%) cases reported with local injury and 76(96.2%) had no such injury. The present findings are consistent with that of Rongpharpi et al.<sup>19</sup> who reported that majority of cases had no injury. The reason could be that most victims were late for examination and most of the acts were consensual.

In our study most of the hymen were found torn with old tear in 47(59.5%), intact in 25(31.6%) and torn with fresh/recent tear in 7(8.9%) of the cases. This finding is similar with the finding of Rongpharpi et al.<sup>19</sup> who reported that most of the cases presented with old hymenal tear. This could be due to late reporting, repeated offences followed by filing of complaints by the victims after the partner's refusal to marry after elopement.

### CONCLUSION

The present study shows that young girls between the age of 14-17 years are more vulnerable to sexual assault. In majority of cases the incident took place in the house of relatives of accuse or his own house. Biggest threat to the victim is not from the strangers but from the known persons. So there is a need to spread awareness among parents and children on sexual crimes and the benefit of early reporting to the police and medical examination, as delay in reporting and examination causes loss in significant trace evidences.

**Conflict of interest:** None.

**Ethical clearance:** Taken.

**Contribution of authors:** We declare that this work was done by the author(s) in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors.

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## ORIGINAL PAPER

# Contraceptive knowledge, practice and acceptance among women seeking termination of pregnancy

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## ABSTRACT

**Background:** The widespread adoption of family planning in a society is an integral component of modern development.

**Objectives:** The study was conducted to assess the contraceptive knowledge, practice and acceptance among women seeking termination of pregnancy at Guwahati Medical College and Hospital. **Methods:** Between 1<sup>st</sup> January, 2015 to 31<sup>st</sup> December 2015, 699 women who were put for Medical termination of pregnancy (MTP) by suction evacuation, after workup and investigation were taken up for the study in Guwahati Medical College and Hospital. They were interrogated on a structured questionnaire. After termination of pregnancy, the contraceptive method opted by the women was noted down. **Results:** Of the 699 women who came for voluntary termination of pregnancy, 594(84.98%) did not use contraception earlier, though (81.69%) women were aware of more than one method of contraception. The request for MTP was on grounds of family being completed (29.61%), previous child was small (25.75%), and financial instability (22.32%). Post abortion 32.47% accepted concurrent sterilisation and 26.04% had an IUCD inserted immediately. **Conclusion:** Though the awareness about various contraceptive methods was high, yet practice of contraception was low. Acceptability was high once the women underwent termination of pregnancy.

**Keywords:** Intra uterine contraceptive device; oral contraceptive pill

## INTRODUCTION

The population explosion is affecting the whole world, particularly detrimental to the infrastructure of developing country like India. There is a definite need of giving utmost importance to regular contraception and emergency contraception.<sup>1</sup> MTP should be offered in case of

unwanted pregnancy. With the use of regular and emergency contraception the need for MTP will be much reduced.<sup>2</sup> Our country is the second most populous in the world having a rapidly growing population and contraceptive practice is the only answer.

**Objectives:** The study was conducted to assess the contraceptive knowledge, practice and acceptance among women seeking termination of pregnancy.

## MATERIALS AND METHODS

In this study conducted in the Department of Obstetrics and Gynaecology, Guwahati Medical College and Hospital, from 1<sup>st</sup> January, 2015 to 31<sup>st</sup> December 2015. A total of 699 women were put for termination of pregnancy by suction evacuation, after examination, workup and investigations. These women were questioned based on a standardised questionnaire. MTP was done and the method opted or taken concurrently was noted down. Those who came with incomplete abortion or underwent MTP for obstetric reason like missed abortion, molar pregnancy, congenital anomalies or came with spontaneous abortion were excluded from the study as they might not be willing to use contraception because they would want a pregnancy. Cases of medical abortion

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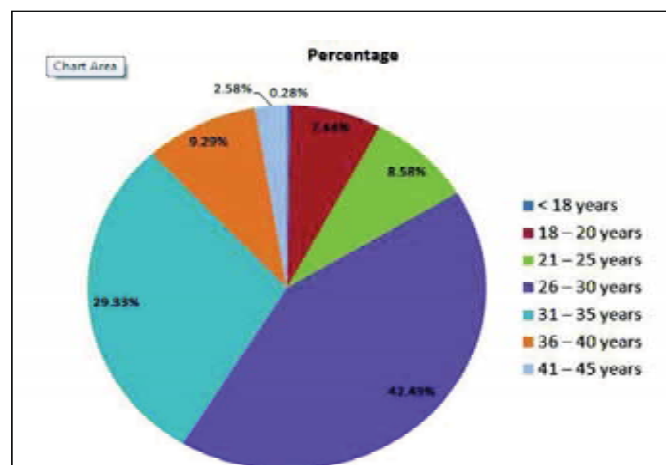
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using mifepristone and misoprostol were excluded as they were mostly lost to follow up and some ended in incomplete abortion for which evacuation had to be performed at a later date.

## RESULTS

In this study 42.49% belonged to the age group of 26 – 30



**Figure 1** Showing Age wise distribution of clients seeking MTP years of the 699 women, 18.31% were not aware of any contraceptive methods. But the majority knew about more than one method of contraception. Though awareness level was high, only 15.02% practiced some form of contraception previously. This is depicted in **Table 1** below.

**Table 1** Awareness of contraceptive methods (Number overlaps as some are aware of more than one method)

Method	Number	Percentage
Female sterilization	566	81%
Condom	450	64.38%
OCP	426	60.94%
IUCD	358	51.22%
Emergency contraception	200	28.61%
Natural methods	98	14.02%
Male sterilization	60	8.58%
Injectables	51	7.30%
Not aware	128	18.31

Most of the women came to know about contraception from family and friends (46.35%), Doctors/nurse/paramedics (43.78%), television (36.62%) and School and College education (32.90%). Majority of termination of pregnancy were done at the gestational age of < 12 weeks (97.57%). This is depicted in **Table 2** below.

**Table 2** Source of knowledge of contraception (Number exceeds as source overlaps)

Source	Number	Percentage
Family members/friends	324	46.35%
Radio	126	18.02%
Television	256	36.62%
News paper/magazine	120	17.17%
Doctors/nurse/paramedics	306	43.78%
School and college education	230	32.90%
No knowledge	128	18.31%

29.61% women did not want a child as their family was complete followed by 25.75% wanted termination as their previous child was small. On questioning whether they regretted that they had to terminate pregnancy, 86.84 had no regret. Out of 699 women who underwent MTP, concurrent sterilization was done in 227 (32.4%) cases and IUCD was given in 182 (26.04%) cases. This is depicted in **Table 3** below.

**Table 3** Reason given by clients for termination of the present pregnancy

Reason	Number	Percentage
Previous child was small	180	25.75%
Family complete	207	29.61%
Pursuing studies	82	11.73%
Financial instability	156	22.32%
Not married	62	8.87%
Contraceptive failure	10	1.43%
Widow (Social cause)	2	0.29

Of the remaining 290 cases majority promised to start oral contraceptive pills. This is depicted in **Table 4** below.

**Table 4** Choice of method for future use by women who did not accept immediate contraception

Method	Number(n=290)
OCP	125
Condom	55
Interval IUCD	50
Female sterilization	20
Male sterilization	2
Injectable	2
Undecided	36

## DISCUSSION

In our study 51% coming for voluntary termination were in the age group of 21–30 years which is comparable to the study by Parvati V, Bhat et al<sup>3</sup> (70%), Sonali Gaikwad et al<sup>4</sup> (37%) and Sanjay R Quraishi et al<sup>5</sup> (75.24%). In this study the percentage of illiterate were only 10.73% which is comparable to Parvati V, Bhat et al.<sup>3</sup> Education, religion and place of residence had no influence in the percentage of women seeking abortion.

In this study 43% of MTP seekers were Para-1, in contrast to Parvati V, Bhat et al<sup>3</sup> where 80.4% women were Para-1.

Awareness level about different contraceptive methods was very high in our study. Only 18.31% were not aware of any method of contraception. Most of the women knew about more than one method. Highest awareness was about female sterilization (81%), which is comparable to the study by Srivastava Reena et al<sup>6</sup> (82.1%) and Sonali Gaikwad et al<sup>4</sup> (82%). Though these women were aware of various contraceptive methods, 84.98% were not practicing any method of contraception which is comparable to the study by Parvati V, Bhat et al<sup>3</sup> (76.3%) and Srivastava Reena et al<sup>6</sup> (55.2%). In the study by Suneeta Mittal et al<sup>7</sup> only 39.1% were not using contraceptive methods earlier. Most of the termination done were <12 weeks (97.57%) in our study comparable to Parvati V, Bhat et al<sup>3</sup> (97.9%). In our study the main reason given for seeking abortion was because the family was complete (29.61%), which is comparable to the study by Sanjay R Quraishi et al<sup>5</sup> (31.25%). The second leading cause for seeking termination of pregnancy was that the first child was very small (25.75%). Financial instability and marital status were two other independent factors determining the outcome of pregnancy in our study. Unfortunately 86.84% did not have any regrets about the termination of pregnancy which is comparable to the study by Parvati V Bhat et al<sup>3</sup> (94.8%).

After termination of pregnancy, 32.47% had concurrent sterilization done and 26.04% had an IUCD inserted immediately. This is comparable to the study by Mukhopadhyay et al<sup>8</sup> on fertility regulation at Kolkata, where 35.8% accepted Copper T and 30% accepted permanent sterilization after MTP as a mode of contraception. The rest of the women decided to opt for a method of contraception at a later date. Even after counseling 36 women (5%) who underwent MTP remained undecided whether to opt for a contraceptive method or not.

There is lack of awareness amongst many women about the availability of regular contraception and emergency contraception makes them more prone to unintended pregnancy and its complications.<sup>9,10</sup>

Among the family planning seekers, the majority of women opted for IUCDs or permanent tubal sterilization which continues to be popular in India.<sup>11-14</sup>

## CONCLUSION

The present study highlights the fact that though awareness about contraceptive methods was high, the use of

contraceptive methods was very low. This is the main reason for a high fertility rate. Hence we recommend spread of correct knowledge about the different contraceptive methods and motivation for contraceptive use by doctors and health workers. The media and non-government organizations (NGO) can play a role to improve the female healthcare in the larger perspective. Another important factor is regular availability of contraceptives and adequate health care services at the peripheral level.

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## ORIGINAL PAPER

# A study of violent asphyxial deaths

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### ABSTRACT

**Background:** Violent asphyxial death is a common incident in forensic practices and is increasing day by day. **Materials and methods:** A Retrospective study of violent asphyxial deaths (116 cases) is done for 4 years brought to the Mortuary of JNIMS, Imphal, Manipur, during the period of January 2014 to December 2017. **Results:** Incidence of violent asphyxial deaths was 14.44% of total autopsies. Hanging is the most commonly encountered violent asphyxial death followed by drowning. The highest incidence was in the age group of 20-30 years (31.89%) followed by 10-20 years (25.86%). Males constitute (58.62%) of the total cases. **Conclusion:** Suicidal death was the most common manner of death. All cases of strangulation and smothering were homicidal.

**Key words:** Hanging; drowning; strangulation; smothering.

### INTRODUCTION

Asphyxia may be defined as a state in which the body lacks oxygen because of some mechanical interference with the process of breathing.<sup>1</sup> Violent asphyxial deaths include hanging, strangulation, smothering, traumatic asphyxia, suffocation, choking and drowning. Hanging is commonly seen in suicidal cases while strangulation is usually homicidal.<sup>2</sup> Accidental hanging can occur among children during playing or in toddlers by slipping of restraining straps, or among athletes who are in habit of exhibiting hanging, or in persons with masochistic or transvestic tendency.<sup>3</sup>

With the increase in crime, the count and variety of medico-legal deaths has increased tremendously in the recent years. Due to population explosion, poverty and increasing stress and strain in our daily life, we frequently come across cases of suicides, homicides and accidents. With urbanization, rural areas are not left aloof and this

can be seen from the increasing incidence of such cases from these areas.<sup>4</sup>

It has been observed that the cases of asphyxial deaths are occurring in huge number in our state. It is becoming more common in the middle age group.

### MATERIALS AND METHODS

The post-mortem report of 116 cases of violent asphyxial deaths which were examined in the Mortuary, Jawaharlal Nehru Institute of Medical Sciences, Imphal, Manipur, during the years 2014-2017 were studied and analysed.

### RESULTS

A total of 803 autopsies were conducted during the period in the mortuary of Jawaharlal Nehru Institute of Medical Sciences, Imphal, Manipur. Out of 803 autopsies, 116 cases (14.44%) were of asphyxial deaths. Maximum cases of asphyxial deaths occurred in the age group of 20-30 years (31.90%), followed by 10-20 years (25.86%), and 30-40 years (18.97%), and least was found in age group 40-50 years and 0-10 years with 5.17% cases each (Table 1).

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**Table 1** Age wise distribution of cases

Sl. No.	Age range (in years)	Frequency	Percentage
1	Below 10	6	5.17%
2	10-20	30	25.86%
3	20-30	37	31.90%
4	30-40	22	18.97%
5	40-50	6	5.17%
6	50-60	8	6.90%
7	Above 60	7	6.03%
	<b>TOTAL</b>	<b>116</b>	<b>100.00%</b>

Out of 116 violent asphyxial deaths, males constitute 68(58.6%) and females 48(41.4%) (**Table 2**).

**Table 2** Sex wise distribution of cases

Sl. No	Sex	Frequency	Percentage
1	Male	68	58.6 %
2	Female	48	41.4%
	<b>Total</b>	<b>116</b>	<b>100.0%</b>

Most of the victims i.e., 57(49.14%) cases were unemployed, of which 35 were suicidal, 15 were accidental and 7 were homicidal in nature, followed by students 31(26.72%) cases of which 15 were suicidal, 10 were accidental and 6 were homicidal in nature. 28(24.4%) of the cases were employed, of which 16 were accidental, 9 were suicidal and 3 were homicidal in nature(**Table 3**).

**Table 3** Distribution of manner of death base on occupation of victims

Sl No.	Occupational Status	Manner of Death			Total	Percentage
		Suicidal	Accidental	Homicidal		
1	Student	15	10	6	31	26.72%
2	Employed	9	16	3	28	24.14%
3	Un-Employed	35	15	7	57	49.14%
	<b>Total</b>	<b>59</b>	<b>41</b>	<b>16</b>	<b>116</b>	<b>100.00%</b>

**Table 4** Distribution of manner of death base on type of asphyxial death

Sl. No	Type of Asphyxial Death	Manner of Death	Male	Female	Total	Total	Percentage
1	Hanging	Suicidal	32	27	59	59	50.9%
		Accidental	0	0	0		
		Homicidal	0	0	0		
2	Drowning	Suicidal	0	0	0	43	37.1%
		Accidental	32	9	42		
		Homicidal	0	1	2		
3	Strangulation	Suicidal	0	0	0	12	10.3%
		Accidental	0	0	0		
		Homicidal	4	8	12		
4	Smothering	Suicidal	0	0	0	2	1.7%
		Accidental	0	0	0		
		Homicidal	0	2	2		
	<b>TOTAL</b>		<b>68</b>	<b>48</b>	<b>116</b>	<b>116</b>	<b>100.00%</b>



The incidence of various asphyxial deaths were recorded and hanging was found to be the most common type with 59(50.9%) cases, of which 32 were male and 27 were female, followed by drowning with 43(37.1%) cases, of which 32 were male and 11 were female, strangulation with 12(10.3%) cases of which 4 were male and 8 were female, smothering with 2(1.7%) cases with female preponderance (**Table 4**).

Regarding manner of death, it is found that all the cases of hanging i.e., 59(50.86%) cases, were suicidal in nature. Accidental and homicidal hanging were not found in the study. All strangulation (10.34%) and smothering (1.72%) cases, were of homicidal in nature and out of 43 cases of drowning (37.06%), 42 were found to be accidental and remaining 1 was homicidal in nature (**Table 4**).

Most of the cases occurred between 6 am – 12 noon with 50 cases contributing 43.1%, followed by between 12 noon – 6 pm with 36 cases (31.0%), 12 midnight – 6 am with 19(16.4%) cases and between 6 pm-12 midnight with 11 cases (9.5%) (**Table 5**).

**Table 5** Distribution of cases base on time of incident

Sl. No.	Time of Incidence	Frequency	Percentage
1	00- 6am	19	16.4%
2	6am - 12noon	50	43.1%
3	12noon-6pm	36	31.0%
4	6pm-00	11	9.5%
	<b>TOTAL</b>	<b>116</b>	<b>100.00%</b>

## DISCUSSION

In the present study, it was found that the incidence of violent asphyxial deaths was 14.44% of the total autopsy cases brought to JNIMS Mortuary, Imphal. This incidence rate closely resembles to the study done by Ghadge MR<sup>5</sup> (12.8%), Gupta Ved Prakash et al<sup>6</sup> (11.54%), Lalwani S et al<sup>7</sup> (11.21%), but contrast with the study done by DK Vadgama<sup>8</sup> (22.2%), who found higher rate of incidence and study done by Momochand A et al<sup>9</sup> (7%) and Chaurasia N et al<sup>10</sup> (6.95%), found lower rate of incidence in their respective studies. Variations of geographical location, culture, ethnicity etc are most probably the reasons for the difference in incidence rate.

In this study, maximum incidence of asphyxial deaths was seen in the age group ranges from 20-30 years followed by 10-20 years of age, contributing 31.90 % and 25.86 % of the total asphyxial deaths respectively. It clearly indicates that young adults are the main victims of asphyxial deaths. The findings of the present study are similar with the study done by Gupta Ved Prakash et al<sup>6</sup> (33.12%), Momochand A et al<sup>9</sup> (33.1%) and Chaurasia N et al<sup>10</sup> (35.79%). Teenage and adulthood are the most active phases of life wherein exposure to anxiety, unemployment, failure in love, increasing stress in daily life, can frequently come across cases of suicides, homicides and accidents.

In our study, males outnumbered females, contributing 58.6% and 41.4% respectively. Similar findings were observed in the study done by Chaurasia N et al<sup>10</sup> (males: 60.89% and females: 39.11%), Reddy SP et al<sup>11</sup> (males: 59.14% and females: 40.86%) Bakkannavar<sup>12</sup> (males: 63% and females: 37%) and Firoz Ahmed et al<sup>13</sup> (males: 61.9% and females: 38.1%). The high incidence among the males may be due to their lifestyle which causes them to confront dangers without thinking that death may result. Males being natural breadwinners of the family are expected to be outdoors most of the time and therefore more exposed to the danger of violence and accidents.

In the present study, a maximum of 49.14% victims were unemployed, followed by students i.e. 26.72% and 24.14% were service holders. Low level of education of the victims found in the study is correlated with the fact that victims either remain unemployed or competition for the job is one of the major anxiety factors among them. Committing suicide is also high, poverty and struggles for survival being the main reason for increasing the incidence of suicide.

In the present study, it was observed that hanging was the commonest method used in deaths due to asphyxiation in our study accounting to 50.86% which was in agreement with the studies done by Chaurasia N et al<sup>10</sup> (52.21%), Reddy SP et al<sup>11</sup> (61.19%) and Sharma BR et al<sup>14</sup> (56.3%). The victims of hanging preferred outside their home for their violent act in this study.

In this study, of all the total asphyxial deaths, suicidal deaths was found to be the highest, followed by accidental and homicidal deaths.

Hanging as the method of suicide, was found to be more prevalent among all suicidal deaths, the reason being it is painless, materials required are easily available, a wide range of ligatures can be used and has a very high mortality rate. Out of the 43 cases of drowning, 42 were accidental and only 1 was homicidal in nature and all the cases of strangulation and smothering in this study were homicidal which is similar with the findings of Lalwani S et al<sup>7</sup>, Chaurasia N et al<sup>10</sup>, Davidson A et al<sup>15</sup>, Majumder BC<sup>16</sup>, Azmak D<sup>17</sup>, Kanchan T et al<sup>18</sup>.

## CONCLUSION

Medico legal autopsies not only give the cause and manner of death but also provide an important statistical data related to legal incidents in the region. Asphyxial deaths accounted for 14.4% of the total studied cases. The most common asphyxial death is hanging followed by drowning. Males were commonly involved than females. Most common age group for such type of death is 20-30 years. Hanging type of death was generally found to be of suicidal manner. Suicidal deaths as a result of hanging and accidental deaths as a result of drowning seems to be the major contributing causes of asphyxial deaths. Both these manner of deaths indicates frustration and carelessness on the part of population. Measures to improve in the fields of education, health, increase in employment opportunities are expected to lessen

the existing stress and strain of the society.

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**Author Declaration:** (1) The article is original with the author(s) and does not infringe any copyright or violate any other right of any third party. (2) The article has not been published (whole or in part) elsewhere, and is not being considered for publication elsewhere in any form, except as provided herein. (3) All author(s) have contributed sufficiently in the article to take public responsibility for it and (4) all author(s) have reviewed the final version of the above manuscript and approved it for publication.

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## ORIGINAL PAPER

# Evaluation of conservative management of uncomplicated acute appendicitis in a rural medical college

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## ABSTRACT

**Introduction:** Acute appendicitis is one of the commonest causes of acute abdomen with life time risk of 7-8%. Currently appendectomy is the favored treatment for acute appendicitis. However, there is wide discussion and controversy on the surgical and nonsurgical treatment of acute uncomplicated appendicitis. **Objectives:** The study was conducted to evaluate the efficacy and outcomes of the conservative management of uncomplicated cases of acute appendicitis. **Materials and methods:** The study was done in department of surgery, Fakhruddin Ali Ahmed Medical College and Hospital, Barpeta, Assam, India, a rural medical college & hospital from January 2014 to December 2016. Patients above the age of 16 yrs with clinical and radiological features of acute appendicitis presenting within 72 hrs of the beginning of abdominal pain were included. All patients received broad-spectrum antibiotics and symptomatic treatment. The follow-up period was 1 year. Patients were informed to report immediately if symptoms reappear or patients underwent appendectomy outside. **Results:** out of the 45 patients evaluated, 27(60%) patients were female and 18 (40%) patients were male with mean age 34 years. Conservative treatment was effective in 34(75.5%) patients and failure encountered in 11(24.4%) patients. No mortality recorded in this study. The main complications which occurred in those patients who failed to respond to conservative treatment were perforated appendicitis (1 patient), appendicular abscess (1 patient) and appendicular lump (2 patients). **Conclusion:** selected cases of uncomplicated acute appendicitis can be treated successfully by conservative treatment. However, conservative treatment needs close monitoring and follow-up along with proper communication to the patient.

**Keywords:** Efficacy; antibiotics; nonsurgical treatment; appendectomy.

## INTRODUCTION

Acute appendicitis is one of the commonest cause of acute abdomen in general surgery practice. Complications of appendicitis include perforation and generalized peritonitis. Currently, appendectomy has been the primary treatment in most cases.<sup>1</sup> However, in 10% of cases the appendix is found to be normal.<sup>1,2,3</sup> Appendectomy can result in many complications such as surgical wound infection, intestinal obstruction due to adhesions, tubal infertility in females and rarely fistula. Non operative management with antibiotics may be a cost-effective alternative to surgery in a large percentage of patients without increasing the risk and may reduce hospital stay and costs in both developed and third world countries.<sup>4</sup> There is considerable discussion regarding the application of conservative treatment compared with surgical treatment in selected cases of acute appendicitis, as few studies have addressed this issue to date.<sup>5,6</sup> Some reports state that immediate appendectomy can be avoided for at least 24 hrs without increasing morbidity if antibiotics are administered.<sup>7,8</sup> Other authors suggest that appendectomy may not be necessary for the majority of patients with acute uncomplicated appendicitis, as the condition resolves spontaneously without the need for a surgical procedure in

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many patients and in others may be treatable with antibiotics alone.<sup>9</sup> This approach has many advantages, including high success and low recurrence rates, reduced morbidity and mortality, less pain, shorter hospitalization and sick leave, and reduced costs.<sup>10</sup> The aim of this study was to evaluate the effectiveness of conservative treatment in uncomplicated acute appendicitis using antibiotics.

## MATERIAL AND METHODS

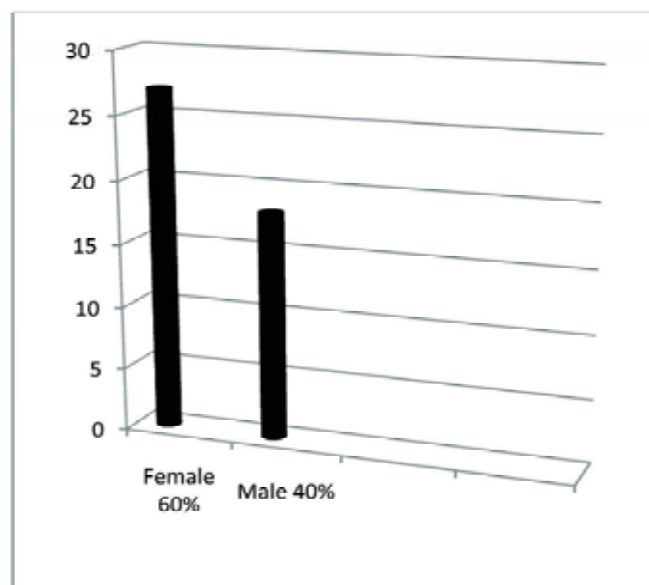
This prospective study was carried out in Fakhruddin Ali Ahmed Medical College between January 2014 to December 2016. Selected 45 patients were enrolled in this study based on the inclusion and exclusion criteria. All patients above 16 years of age with a history of pain in right iliac fossa for less than 72 hrs and clinically diagnosed as the first attack of appendicitis were included in this study. Ultrasound of abdomen was done for all patients to confirm the clinical diagnosis of acute appendicitis. Patients having perforation, abscess, lump on clinical examination and radiological reports were excluded along with patients unwilling for conservative management. All patients meeting the inclusion criteria then admitted to the hospital and received intravenous antibiotics (cefotaxime 1 g twice daily and metronidazole infusion 500 mg/100 ml 3 times per day) for 5 days along with intravenous fluids, no oral intake with 6 hourly charts for temperature, blood pressure, pulse rate, respiratory rate and local abdominal sign. Patients who did not respond to conservative treatment or worsened were operated by appendectomy. Patients were told to contact immediately if pain recurs, vomiting and fever had occurred. Follow-up was done for one year at interval of three months. Patients were told to inform us if they underwent an operation outside.

**Statistical analysis:** Statistical package for social science version 20 (SPSS 20) was used for both data entry and data analysis. Discrete variable presented as number (%). Chi-square test (or fisher exact test when appropriate) used to test the significance of association for the discrete variable. p-value of <0.05 were considered significant.

## RESULTS

Out of 45 cases 27 patients were female and 18 patients were male (**Figure 1**). Age distribution is shown in **Table 1**. Age ranged between 16 and 60 years. The maximum number of patients (42%) belonged to age group 20-29 years. 30(66.6%) patients presented with signs and symptoms of acute appendicitis to the hospital with time interval <24 hrs, 8(17.7%) patients presented with time interval 24-48 hrs and 7(15.5%) patients presented with time interval 48-72 hrs as shown in **Table 2**. Out of 45 patients, 34(75.5%) patients were successfully managed with conservatively. In the remaining 11(24.4%) patients, conservative treatment failed. Failure to respond to treatment was seen in 5 patients (11%) during initial admission whereas recurrence was seen in 6 patients (13.3%) cases during follow up period (**Figure 2**).

Of the 11 patients who failed to respond to conservative treatment, 5 patients were operated after 2 days of treatment,



**Figure 1** Sex distribution of the study

**Table 1** Age distribution of the study

Age (years)	No. of patients (%)
<19	3 (6.6)
20-29	19 (42.2)
30-39	12 (26.6)
40-49	9 (20)
>50	2 (4.4)
<b>Total</b>	<b>45 (100)</b>

**Table 2** Number of the patients according to the duration of presenting symptoms

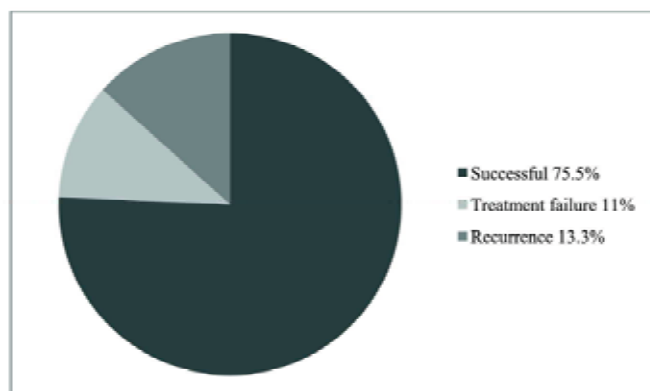
Hours of attack of appendicitis	No. of the patients (%)
<24 h	30 (66.6)
24-48 h	8 (17.7)
48-72 h	7 (15.5)
<b>Total</b>	<b>45 (100)</b>

2 patients were operated after completion of treatment course after 7 days and 4 patients were operated during the follow-up period of 1 year as shown in **Table 3**. Among the operated patients, 1 patient had perforated appendix, 1 patient had appendicular abscess and 2 patients had appendicular lumps.

## DISCUSSION

Appendectomy has been regarded as the gold standard for treatment of acute appendicitis. The mortality rate of appendectomy ranges from 0.07 to 0.7 and from 0.5 to 2.4 without and with perforation, respectively. Antibiotic





**Figure 2** Outcome of conservative treatment

**Table 3** Appendectomies after trial of conservative treatment

Time of interval appendectomy	No. of the patients(n = 11)
Surgery after 48 h of treatment	5
Appendectomy after 7 days of treatment	2
Appendectomy within 1 year	4

treatment can reduce the mortality and morbidity risk associated with surgery. Antibiotics give the chance to treat acute appendicitis when surgical means are not readily accessible particularly in rural areas of developing countries and isolated areas. Conservative treatment is associated with less cost effect balanced to surgery.<sup>11</sup>

In the present study, 34 patients out of 45 patients were successfully treated with conservative method and 5 patients (11%) failed to respond to conservative treatment and had been operated and further 6 patients (13.3%) showed recurrence of appendicitis during the follow-up period. Thus 11 patients failed to respond and the failure rate was 24.4%. In a similar study done in Sahlgrenska University Hospital (between May 2009 and February 2010) involving 442 patients show that 342 patients (77.4%) treated conservatively successfully and 100 patients (22.6%) failed to respond to conservative treatment,<sup>12</sup> which nearly resemble our study results. Another study which was done in the surgical department of GMERS Medical College, Gandhinagar between years 2011-2013, that involve a sample of 30 patients undergoing conservative management show that 21 patients (70%) treated conservatively successfully and 9 patients (30%) failed to respond conservatively.<sup>13</sup> Our study results also agree with a recent study done in India in 2016 by Gedam PS. Et al which involved 71 patients and showed a successful rate 74.65%, treatment failure rate 14.08% and recurrence rate 13.11%.<sup>14</sup> We used third generation cephalosporin and metronidazole in all our patients, similar to most randomized control trials.

## CONCLUSION

Conservative treatment can be applied safely in the majority

of cases of the first attack of uncomplicated acute appendicitis, avoiding appendectomy and its associated morbidity and mortality. However, conservative treatment needs close monitoring and follow up of the patients. Treatment failure after conservative treatment is of low incidence and acceptable to the patient.

**Ethical clearance:** Taken.

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## ORIGINAL PAPER

# Effect of structured teaching programme on knowledge of substance abuse among adolescents

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### ABSTRACT

**Introduction:** Substance abuse is one of the major health challenges across the world. Adolescence is the transitional stage of physical and mental human development with substantial risk for initiating substance abuse. **Objectives:** To evaluate the effect of structured teaching programme on knowledge of substance abuse among adolescents. **Methods:** Evaluative research approach and pre-experimental one group pre- test and post- test research design was adopted for the study. One hundred twenty adolescents in the age group of 12 to 17 years studying in VII, VIII and IX were selected through proportionate stratified random sampling technique by using lottery method. Structured self-administered questionnaire was used to assess the pre-test knowledge. A structured teaching programme was prepared on substance abuse and administered followed by a post-test after seven days. **Results:** Out of 120 adolescents in pre-test knowledge, majority 94(78.3 %) had moderately adequate knowledge, 20(16.7%) had inadequate knowledge and 6(5%) had adequate knowledge. After administration of structured teaching programme during post-test only 7(5.8%) had moderately adequate knowledge, none of them had inadequate knowledge and majority 113(94.2%) had adequate knowledge. The mean post –test knowledge scores 22.51 was significantly higher than the mean pre-test score 11.6 as evident from 't' value 31.054 for df 119 at 0.05 level of significant. **Conclusion:** The structured teaching programme was effective in improving the knowledge on substance abuse among adolescents.

**Keywords:** Pre-experimental study, assess, self-administered questionnaire.

### INTRODUCTION

Substance abuse among adolescents has become a global challenge and also an important health concern and for the

past two decades there has been a dramatic increase in the demand for interventions to address the substance abuse problem. This demand has led to the development of multiple primary, secondary and tertiary substance abuse prevention programmes.<sup>1</sup> In India, the prevalence of substance abuse which is generally low in early adolescence aged 12 and 13 rises –steeply in the late teen age and is highest during the early 20's.<sup>2</sup> Campus atmosphere and peer pressure is forcing and influencing the adolescent students to indulge in alcoholism mainly due to lack of adequate knowledge about the consequences of its use or falsely perceived knowledge and attitude towards alcoholism as the students use alcohol for “company, festivity or curiosity”.<sup>3</sup> A study revealed that most of the young substance users started taking substances between age of 14 to 18 years and the largest member being found to be at the age of 16 and 17 years. This study further suggests that about 35 to 40 per cent of the adolescents agreed that they tried gateway substances like alcohol and tobacco.<sup>4</sup>

Time and again it has been proven that schools can provide an ideal platform for the prevention of substance abuse.

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School can provide a supportive environment for promoting good adolescence health and they can also be extremely helpful in spreading the right message to the local community.

The objectives of this paper are to assess the pre-test knowledge of substance abuse and the effect of structured teaching programme on knowledge of substance abuse among adolescents.

## MATERIALS AND METHODS

**Study Design:** Experimental design, to assess the effect of structured teaching programme on knowledge of substance abuse among adolescents.

**Sampling technique:** Purposive sampling

**Study population:** Selected High Schools of Kamrup Metro, Assam, viz., Maligaon High School, Maligaon and Tetelia High School, Gotanagar. Students of class VII, VIII and IX by using proportionate stratified random sampling technique with lottery method.

**Data collection tools and techniques:** A pretested and predesigned questionnaire was used to assess the knowledge of substance abuse among adolescents.

### Study variables

Demographic variables consisted of age, education, gender, types of family, monthly income of the family, occupation of the father and occupation of the mother, no. of siblings, birth order, family history of substance use and availability of easy sources of substance.

Variables in relation to questionnaire to assess the knowledge of adolescents before and after administering structured teaching programme regarding substance abuse. In the final draft the questionnaire consists of 25 items.

Each question has only one correct answer. For each correct answer score 'one' (1) was given and for wrong answer 'zero' (0) was given. The maximum score was 25.

The reliability of the tools was done by Cronbach's alpha method. Findings of the study revealed that the tool was found to be reliable. The reliability of knowledge was 0.86. Before starting the final data collection procedure for the present study; the investigator obtained permission from the institutional ethical research committee of Regional College of Nursing, Guwahati, Assam. Permission was obtained from authorities of selected High schools of Kamrup, Metro, Assam. The data collection period was scheduled from 24th January 2017 to 2nd March 2017. The purpose and importance of the study was explained by the investigator to the adolescents prior to data collection and keeping in mind the ethical aspect of research. Data was collected after obtaining informed

**Table 1** Level of knowledge based on scores regarding substance abuse

Level of knowledge	Score range
Adequate (Mean + SD)	Above 15
Moderate (Mean -SD to Mean + SD)	8 to 15
Inadequate (Mean - SD)	Below 8

consent of the adolescents for their willingness to participate in the study. A pre-test was conducted to the selected adolescents for 30 minutes with structured self-administered questionnaire. After the pre-test, a structured teaching programme on substance abuse of 45 minutes was implemented on the same day. All the study subjects were informed regarding the post-test which was scheduled exactly after one week of the implementation of the structured teaching programme. The data analysis was consisted of descriptive and inferential statistics.

## RESULTS

The data were grouped and analysed under following sections:

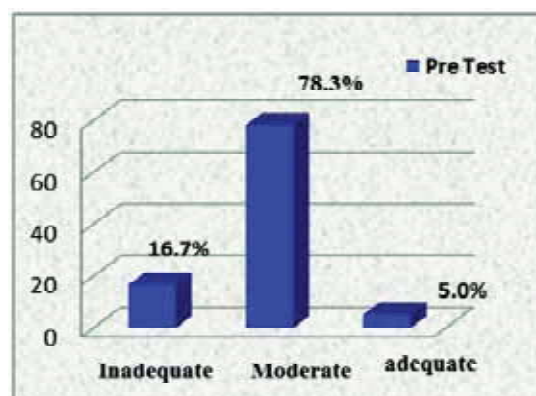
a) Frequency and percentage distribution of adolescents according to demographic characteristics

Out of 120 respondents, equal number of respondents i.e., 60(50%) were from each age group 12-14 and 15 -17 years. Majority of the respondents 53(44.1%) were from class IXth standard. 61(50.8%) were male respondents. The highest percentage of respondents 63(52.5%) were belongs to nuclear family. Majority of the respondents 31(25.8%) had monthly family income Rs. 6, 851 -Rs 17,150. Maximum no. of 66(55%) of the respondents' father and 47(39.2%) of mothers had occupation as business. Highest percentage of respondents 48(40%) had two siblings. 48(40%) of respondents had birth order second. Maximum 66(55%) of the respondents had no family history of substance use. Majority of the respondents 83(69.2%) were agreed availability of easy sources of substance within 100 meters radius of the school.

b) Assessment of pre-test knowledge of adolescents regarding substance abuse n=120

**Figure 1** depicts that out of 120 respondents in pre-test, majority 94(78.3%) of the respondents had moderately adequate knowledge on substance abuse, 20(16.7%) had inadequate knowledge and only 6(5%) had adequate knowledge. Thus, the finding indicates that there is lack of knowledge regarding substance abuse among adolescents.

c) Effect of structured teaching programme on substance abuse



**Figure 1** Respondents in terms of pre-test knowledge scores on substance abuse

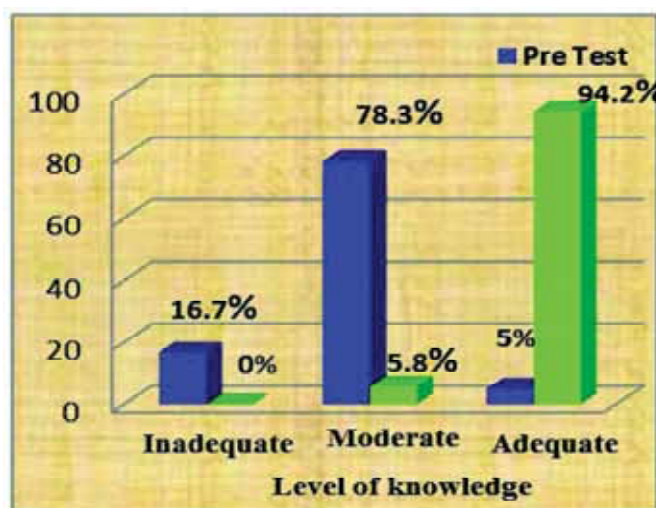


The data presented in **Table 1** shows that in the pre test of respondents 94(78.3%) have moderately adequate knowledge, 20(16.7%) have inadequate knowledge and only 6(5.0%) have adequate knowledge whereas in the

post test, only 7(5.8%) had moderately adequate knowledge, none of respondents had inadequate knowledge and majority 113(94.2%) had adequate knowledge on substance abuse.

**Table 1** Pre-test and post test knowledge scores in terms of frequency and percentage (n=120)

Level of knowledge	Score range	Pre-test		Post-test	
		f	%	f	%
Inadequate	<8	20	16.7	.....	
Moderate	8-15	94	78.3	7	5.8
Adequate	>15	6	5.0	113	94.2
<b>Total</b>		<b>120</b>	<b>100</b>	<b>120</b>	<b>100</b>



**Figure 2** Comparison of pre-test and post-test knowledge score on substance abuse

**Table 2** Paired 't' test between pre-test and post-test knowledge scores on substance abuse (n=120)

Knowledge	Mean	Std. Dev	df	't'	pvalue	Remarks
Pre	11.6	3.22	119	31.054	0.000	S**
Post	22.51	2.46				

The data presented in **Table 2** shows that the mean post test knowledge scores (22.51) is significantly higher than the mean pre-test score (11.6) as evident from 't' value 31.054 for df 119 at 0.05 level of significant. Hence, the scores of post test (SD  $\pm$  2.46) is less dispersed than the score of pre-tests (SD  $\pm$  3.22).

Therefore, it can be interpreted that the knowledge of adolescents on substance abuse has been increased significantly in the post test and that the structured teaching programme is highly effective.

d) Association of pre-test knowledge with selected demographic variables

The study shows that there was no significant association

between pre-test knowledge and selected demographic variables such as age, education, gender, types of family, occupation of the father, occupation of mother, number of siblings, birth order and availability of easy sources of substance. It is therefore concluded that pre-test knowledge is independent from the above parameters. In other words; these factors can't influence on the findings of the present study. However, significant p-value, i.e., ( $<0.05$ ) witnessed in case of family history of substance use reveal that there is certain link of this factor with the pre-test knowledge.

## DISCUSSION

The present study reveals majority 94(78.3%) of the adolescents had moderately adequate knowledge on substance abuse. The present study was in accordance with study conducted by Ganakshi D, Sakun S, Poudel S (2014).<sup>5</sup>

On evaluating the effect of structured teaching programme on knowledge of substance abuse among adolescents showed that the adolescents had lack of knowledge regarding substance abuse. This study was found to be similar with results of Tuppad B S (2014).<sup>6</sup>

Association between pre-test knowledge on substance abuse with selected demographic variables reveals no significant association between pre-test knowledge score and selected demographic variables except the family history of substance abuse. The study was supported by the study of Benitto JA.<sup>7</sup>

## CONCLUSION

The study was conducted to find out the effect of structured teaching programme on substance abuse among adolescents. The finding of the study showed that in the pre-test, majority 78.3% of the adolescent had moderately adequate knowledge, 16.7% had inadequate knowledge and only 5% had adequate knowledge regarding substance abuse. After administration of structured teaching programme, in post-test only 5.8% had moderately adequate knowledge, none of them inadequate knowledge and majority 94.2% had adequate knowledge regarding substance abuse. The mean post-test knowledge scores 22.51 was significantly higher than the mean pre test score 11.6 as evident from 't' value 31.054 for df 119 at



0.05 level of significant .So the findings reveals that the knowledge of adolescents on substance abuse increased significantly in the post test . There was no significant association found between pre-test knowledge scores and selected demographic variables except family history of substance use. On the basis of the findings of the study, it can be concluded that the structured teaching programme is effective in improving the knowledge of adolescents regarding substance abuse.

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**Conflict of interest:** None.

**Ethical clearance:** Taken.

**Source of finding:** None declared.

**Author declaration:** We declare that this work is done by the authors named in this article and all liabilities pertaining to the claim relating to the content of this article will be borne by the authors.

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## ORIGINAL PAPER

# Immunohistochemical expression of Ki-67 and p53 in colorectal carcinoma

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## ABSTRACT

**Objectives:** To investigate the expression of Ki-67 and p53 in colorectal carcinomas and to correlate expression patterns of these markers with histopathological grades of colorectal carcinoma. **Materials and methods:** We determined immunohistochemically the expression of Ki-67 and p53 antibodies in 62 cases of colorectal adenocarcinomas. **Results:** Mean Ki-67 index in our study was 33.9%. Mean Ki-67 increased with dedifferentiation of tumor (Grade I-18.8%, Grade II-33.2%, Grade III-49.1%). The difference in mean Ki-67 index is statistically significant with histopathological grade. ( $p < 0.001$ ). p53 overexpression was seen in 69.3% cases. Percentage of diffuse p53 positivity increased with dedifferentiation of tumor. p53 positivity rate was observed in 22.2% cases of well differentiated carcinoma and increased from 76.2% to 81.8% in moderately to poorly differentiated carcinoma. However, the difference was statistically insignificant with histopathological grade. **Conclusion:** As the result of this study it is concluded that in colorectal carcinoma Ki-67 LI correlated with grade and increases with the dedifferentiation of tumor and also p53 over expression increases with dedifferentiation of tumour. Thus, the evaluations of expression of p53 and Ki-67 can be used as a poor prognostic marker allowing the identification of aggressive forms.

**Keywords:** Histopathology; immunohistochemistry; Ki-67 labelling index.

## INTRODUCTION

Colorectal cancer (CRC) is the fourth most common malignancy with over one million new cases and over 5,00,000 deaths each year worldwide.<sup>1</sup> Incidence of colorectal cancer varies widely, with higher incidence rates in North America, Australia and Europe. Developing countries have lower rates; particularly Africa and Asia.<sup>2</sup> However, with

Westernization of lifestyle, the incidence of colorectal cancer is nowadays increasing in many developing countries also. Surgery still remains the primary treatment modality and pathological examination of resected specimen is a powerful tool for assessing the prognosis.<sup>3</sup>

The p53 gene mutation is related to carcinogenesis in most malignant diseases and has been widely studied. More articles reveal that their immunostain could predict the colorectal carcinoma prognosis. The p53 protein is encoded by a gene p53, located on the short arm of chromosome 17, a frequent site of allelic loss in many tumors. The wild p53 maintains the integrity of genes by detecting mutations and preventing the division of cells with damaged DNA. It blocks the cells in G1 phase of cellular cycle. In colorectal carcinoma, the gene p53 may be rearranged and p53 protein may be altered. Therefore, the replication errors and deregulation of cell growth could appear. According to literature, the deletion of p53 gene with the overexpression of p53 protein is correlated with a lower rate of survival, thus being an independent prognostic factor.<sup>4</sup>

Ki-67 is a nuclear antigen, which is expressed in proliferating cells from G1 to M-phase of the cell cycle. Many studies

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have shown a predictive role of Ki-67 in a wide range of human malignancies, including gastrointestinal stromal tumours, gastrointestinal neuroendocrine tumours, and prostate and breast cancer.<sup>5</sup> Quantification of cell proliferation activity in neoplasms has been targeted with the help of Ki-67 antibody.

The present study was conducted to study the combined immunoexpression of Ki-67 and p53 protein in colorectal carcinomas and to correlate expression patterns of these markers with histopathological variables of colorectal carcinoma. The present study evaluated their role in colorectal carcinoma in our set up.

## MATERIALS AND METHODS

This is a hospital-based study, done in Department of Pathology, Silchar Medical College and Hospital. We studied 68 consecutive cases of colorectal carcinomas over a period of 2 years (2015 to 2017). But we considered only adenocarcinomas for further study, excluding the mucinous carcinomas and carcinoid. 62 cases of colorectal adenocarcinomas were studied. Blocks were retrieved and H&E staining done. The tumor was then graded as well, moderate and poorly differentiated according to WHO grading criteria. Diagnosis of a colorectal carcinoma as a grade III tumor is done when the poorly differentiated component comprises > 50% of the tumor.<sup>6</sup>

Immunohistochemistry for p53 and Ki-67 were done. Sections (4 $\mu$ ) from formalin fixed paraffin embedded tissue blocks were stained by standard immunohistochemical methods using horseradish peroxidase-linked antibody.

The following primary antibodies were used: antibody to p53 (DO7) (mouse monoclonal antibody, prediluted, CELL MARQUE), antibody to Ki-67 (SP6) (Rabbit monoclonal antibody, prediluted, CELL MARQUE).

**The positive controls** used were sections of infiltrating duct carcinoma of the breast for both p53 and Ki-67 antigen. **The negative controls** used were sections of the study tissues with no primary antibody incubation.

## RESULTS

Statistical analysis was done using **Chi square test** and **ANOVA**.

Ki 67 nuclear staining was regarded as positive whereas cytoplasmic staining was considered as artifact. Ki-67 immunostaining index was interpreted as **Labelling index (Ki-67 LI)** = Number of nuclei showing positive staining (brown color)/total number of nuclei  $\times$  100 (in 40 X magnification). MIB-1 labelling index (LI) was determined by counting about 500 tumor cells.

A tumor was considered positive with significant proliferating activity only if nuclear Ki-67 accumulation was identified in at least 10% of all malignant cells in a tissue section.

In p53 immunostaining, 10% or more stained malignant nuclei were scored as positive, regardless of the staining intensity. If fewer than 10% of the nuclei were stained, the slide was scored as negative. The staining distribution was either focal

or diffuse.

Out of the 68 total cases of colorectal cancer, 62(91.1%) cases were adenocarcinoma, 4(5.9%) cases were mucinous carcinoma, and 2(2.9%) were signet ring carcinomas. Only cases of colorectal adenocarcinoma were studied. Age of the patients ranged from 30 years to 75 years, (mean  $57.8 \pm 1.2$  years). Males (66.1%) were more commonly affected than females (33.9%).

The rectum was the most common affected site contributing to 38 cases (61.2%) followed by ascending colon with 14 cases (22.6%), caecum 6 cases (9.7%) and descending colon 4 cases (6.5%). Most common histopathological type were moderately differentiated adenocarcinoma accounting for 67.7% cases. Well differentiated and poorly differentiated cases were 14.5% and 17.8% cases respectively.

In our study, positive nuclear immunohistochemical staining for Ki-67 antibody was seen in all 62 colorectal carcinomas. Ki-67 LI ranged from 7% to 53%. The mean Ki-67 LI was 33.9%.

**Table 1** Expression of Ki-67 in different grades of colorectal adenocarcinoma

GRADE	Ki-67 LI values				
	Minimum	Maximum	Range	Mean	SD
Well differentiated	7	34	27	18.8	$\pm 9.03$
Moderately differentiated	23	41	18	33.2	$\pm 4.08$
Poorly differentiated	42	53	11	49.1	$\pm 4.08$

From **Table1**, it is seen that mean Ki-67 index was 18.8% in grade I, 33.2% in grade II, 49.1% in grade III. The difference in mean Ki-67 index was statistically significant with histopathological grade.  $p < 0.0001$ , highly significant Anova.

**Table 2** Expression of p53 in different grades of colorectal adenocarcinoma

Histopathologic grade	P 53 +	P 53 -
Well differentiated	2(22.2%)	7 (77.8%)
Moderately differentiated	32(76.2%)	10 (23.8%)
Poorly differentiated	9 (81.8%)	2(18.2%)

$p \leq .003$

In our study, it is seen that p53 overexpression was seen in 69.3% of cases. From **Table 2**, it is seen that the positivity increased with increase in the histopathological grade. p53 positivity rate was observed in 22.2% cases of well differentiated carcinoma and increased from 76.2% to 81.8% in moderately and poorly differentiated carcinoma. This difference was statistically significant.

In our study, we found p-53 immunostaining was diffuse (i.e. more than 50% of the cells stained ) in 42.8% cases and

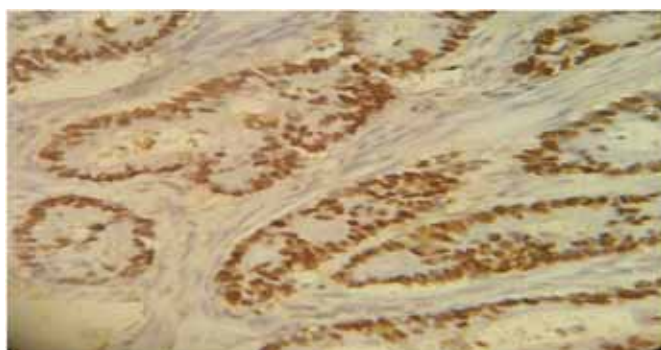


focal (i.e., 5-50% cells stained) in 57.2% cases.

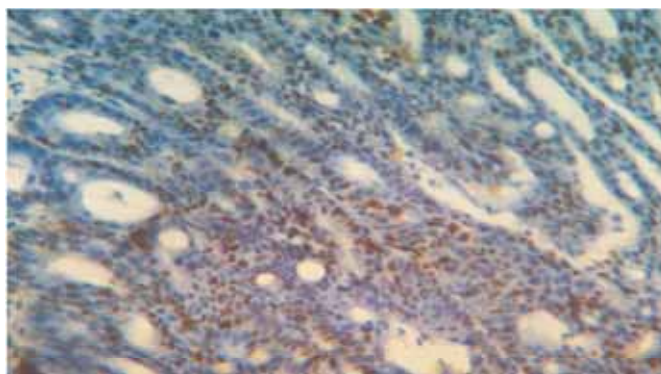
**Table 3** Percentage of cases with diffuse p53 distribution in different grades of colorectal adenocarcinoma

Grades	Percentage of cases with diffuse distribution of p53
Well Differentiated	31.4%
Moderately Differentiated	40.5%
Poorly Differentiated	59.6%

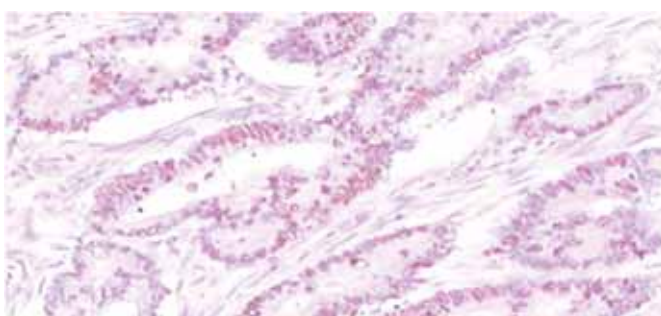
From **Table 3**, it is seen that diffuse p-53 distribution was seen in 31.4% cases of well differentiated cases, 40.5% of moderately differentiated cases and 59.6% of the poorly differentiated cases.



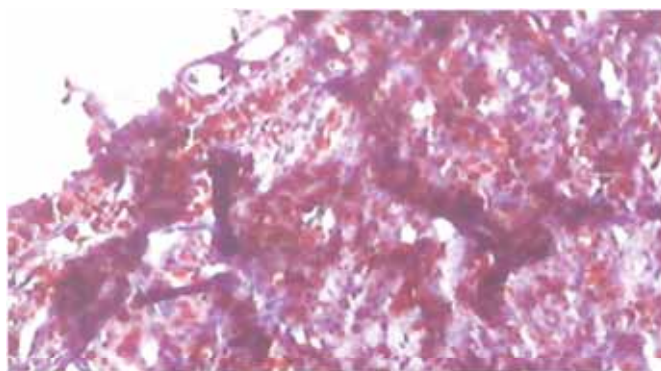
**Figure 1** Ki-67 staining in well differentiated adenocarcinoma colon



**Figure 2** Ki 67 staining in moderately differentiated adenocarcinoma colon



**Figure 3** p53 staining of well differentiated adenocarcinoma colon



**Figure 4** p53 staining in poorly differentiated carcinoma colon

## DISCUSSION

In our study, the mean age of colorectal cancer was found to be  $57.8 \pm 1.8$  years, which is in accordance with the study done by Nayak et al<sup>7</sup> where mean age was  $55.6 \pm 1.2$  and Peedikayil et al<sup>8</sup> where mean age was 58.4 years. In this study, it was found that rectum was the most common site affected contributing to 61.2% cases, followed by ascending colon 22.6%, caecum 9.7% and descending colon 6.5% cases. Peedikayil et al<sup>8</sup> found 74% of the tumors were located distal to the splenic flexure, Nayak et al<sup>7</sup> reported sigmoid colon to be the commonest site followed by cecum and rectum.

**Table 4** Comparison of Mean Ki-67 index in different studies

Study	No. of cases	Mean Ki-67 Index
Ihmann et al. <sup>9</sup>	43	32.8%
Komal Mahendra et al. <sup>10</sup>	47	34.7%
Saleh et al. <sup>11</sup>	52	38.12%
Porschen R et al <sup>12</sup>	61	38.7%
Claudia et al. <sup>13</sup>	41	48%
Palmquist R et al. <sup>14</sup>	56	43.7%
Present study	62	33.9%

In the above studies (**Table 4**), CRCs showed a wide range of Ki-67 LI, ranging from 32-50% indicating a variation in proliferative activity. The mean Ki-67 index in our study was 33.9%. This is in accordance with the study done by Ihmann et al<sup>9</sup> in which Ki-67 LI was 32.8%, Komal Mahendra et al<sup>10</sup> LI was 34.7%, Saleh et al<sup>11</sup> LI was 38.1% and Porschen et al<sup>12</sup> LI was 38.7%. However, Claudia et al<sup>13</sup> and Palmquist et al<sup>14</sup> found a bit higher levels of LI of 48% and 43.7% respectively. Ki-67 has a prognostic and/or predictive value in different tumor types. Some newer studies<sup>15</sup> established the fact that an increased expression of Ki-67 indicates a better survival in rectal and recto sigmoid cancer as these



tumors have better response to radiotherapy.

In this study, Ki-67 immunostain was positive in all the cases of adenocarcinomas. The mean values for Ki-67 LI for well, moderate and poorly differentiated lesions were 18.8%, 33.2% and 49.1% respectively, and the difference was statistically significant ( $p < 0.0001$ ). A strong positive significant correlation between Ki-67 LI and histopathological grade was found. In our study, mean values for Ki-67 LI increased with increase in grades of colorectal carcinoma. This in accordance with studies done by Amway Sen et al<sup>16</sup> who found that the Ki-67 LI increased with the histological

grade of adenocarcinomas. There was a strong positive significant correlation between Ki-67 LI and histopathological grade in their study. Georgescu et al<sup>19</sup> found that the Ki-67 LI increased with the histological grade of adenocarcinomas. Also, in studies done by Claudia et al,<sup>13</sup> Saleh et al,<sup>11</sup> Simona et al,<sup>20</sup> Azza et al<sup>15</sup> the mean Ki-67 index increased with grade of tumor or dedifferentiation of the tumor. In contrast to these studies, other studies by Uzma et al<sup>21</sup> and Ishida et al.<sup>22</sup> found that Ki-67 index was lower in cancers with poor differentiation.

**Table 5** Comparison of Mean Ki67 index with histological grade of tumor

Mean Ki-67 Index/ Grade	Amway et al. <sup>16</sup>	Claudia et al. <sup>13</sup>	Saleh et al. <sup>11</sup>	Ishida et al. <sup>20</sup>	Present study
Well Differentiated	14.25%	20%	35.7%	57.7%	18.8%
Moderately Differentiated	31.64%	34%		60.9%	33.2%
Poorly Differentiated	43.08%	57%	48.3%	46.6%	49.1%

From **Table 5**, a comparative study of Ki67 LI in different studies is being made. It is seen that in these studies Ki 67 LI increases with increase in grades of colorectal carcinoma except in studies done by Ishida et al.

Detection of p53 overexpression by immunohistochemistry is based on the accumulation of p53 protein in cells. In this study, p53 overexpression was seen in 69.3% of cases. The positive cases increased with the increase in the histopathological grade and results were statistically significant.

#### Comparison of p53 positivity rate in different studies:

The frequency of p53 over expression ranged from 58% to 70% in different studies. However, this wide range of p53 positivity is due to inter-study variations, including different antibodies, scoring systems, cut-off values, and study populations. The p53 overexpression in our study was found in 42 cases (69.3%). This is in accordance with study done by Saleh et al<sup>11</sup> where p 53 overexpression was seen in 67.3% cases. p53 overexpression was also seen in some previous reported studies such as Yamagiwa H et al<sup>17</sup> 60.6%, Claudia et al<sup>13</sup> (58.5%), Yong Shin et al<sup>18</sup> (60.9%), Komal et al.<sup>10</sup> (72.3%)

#### Comparison of p53 positivity rate with histological grade

In respect to cell differentiation we found that the p53 positivity increased with the dedifferentiation of tumors. The results were statistically significant. This was in accordance to study by Claudia et al.<sup>13</sup> But Saleh et al<sup>11</sup> found that p53 positivity rate decreased with dedifferentiation though it was not statistically significant.

#### Comparison of cases with focal and diffuse p53 positivity:

In this study 57.2% cases showed focal p 53 positivity and 42.8% cases with diffuse p 53 positivity. This is in accordance with study done by Claudia et al<sup>13</sup> where 58.3% cases had focal p53 positivity and 41.6% cases had diffuse p53 positivity. However, Komal et al<sup>10</sup> found that 17.65% cases had focal p 53 positivity and 82.35% cases had diffuse p53 positivity.

#### Comparison of percentage of cases with diffuse p53 positivity with histological grade of tumor:

In this study, diffuse p53 positivity was found in 31.4% cases of well differentiated, 40.5% and 59.6% in moderate and poorly differentiated colorectal adenocarcinoma respectively. The high p53 positive rate in high grade adenocarcinomas suggest that p53 is involved in cell dedifferentiation in colorectal adenocarcinomas. This is in accordance with study by Claudia et al<sup>13</sup> and Komal et al.<sup>10</sup>

#### CONCLUSION

As the result of this study it is concluded that in colorectal carcinoma Ki-67 LI correlated with grade and increases with the dedifferentiation of tumor and also p53 positivity rate increases with dedifferentiation of tumour. Thus, the evaluations of markers expression p53 and Ki-67 can be used as a poor prognostic marker allowing the identification of aggressive forms. This can also help in selecting patients for targeted therapies in near future.

**Conflict of Interest:** None.

**Ethical Clearance:** Taken.

**Contribution of Authors:** We declare that this work was

done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. The study was conceived, designed by Dr. Mili Das and co-authors along with data collection. Statistical analysis was carried out by Dr. Mili Das.

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## CASE REPORT

# Appendicitis as a cause of small bowel obstruction in pediatric age group

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## ABSTRACT

*Intestinal obstruction is a common surgical emergency in children caused by varied conditions. Although bowel paralysis accompanying acute appendicitis is well known, obstruction of large or small intestine caused by appendicitis is extremely rare with very few cases reported in literature. The diagnosis of such a condition is possible only on table. Every emergency surgeon needs to be aware of such a possibility. We report a case of a 6-year-old male presenting with classical features of intestinal obstruction for 4 days with no history and clinical finding suggestive of an episode of appendicitis. On laparotomy small bowel obstruction was seen and appendix was found to be the cause. We reviewed literature to find similar cases reported in the past.*

**Keywords:** Right iliac fossa tenderness; intestinal obstruction; laparotomy.

## INTRODUCTION

Intestinal obstruction is one of the common causes of acute abdomen in children. Although appendicitis causing intestinal obstruction is a rare cause with only a few reported cases in literature, among the cases there has been only one report of this occurrence in pediatric age group.<sup>1</sup> Mechanical obstruction, with or without strangulation, can result from loops of the small bowel becoming entangled and pinched by the inflamed appendix, or adhesion of the distal end of the appendix to loops of the small bowel, caecum, or retroperitoneum.<sup>2</sup> Here we report a case where the inflamed appendix caused a band like structure resulting in intestinal obstruction.

## Case History

A 6-year-old male child presented with abdominal pain with vomiting for 4 days with constipation for 3 days. Abdomen was distended with tenderness elicited on the palpation of lower abdomen. Per rectal examination was done to rule out

fecal impaction or mass and was found to be normal.

X-ray plain picture erect abdomen showed dilated bowel loops suggestive of bowel obstruction. A diagnosis of mechanical intestinal obstruction of unknown etiology was made and was scheduled for emergency laparotomy. The abdomen was then opened by an upper right transverse incision. Dilated bowel loops were identified and inflamed appendix was seen lying over the distal ileum and tip was attached to the ileocecal mesentery resulting in a band like structure causing obstruction. Band was released followed by appendectomy. Post-



**Figure 1** On table picture showing the appendix acting as an obstruction band over distal ileum

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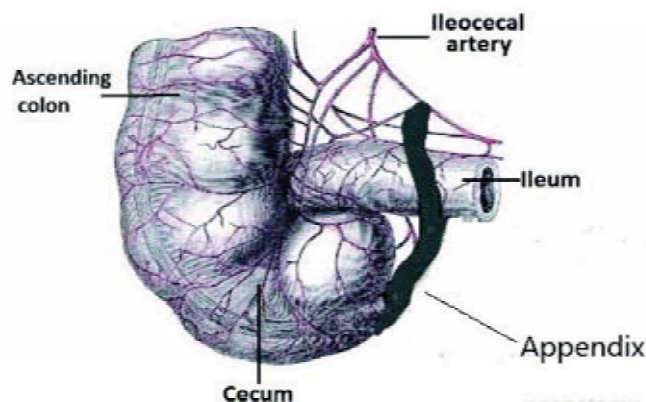
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operative period was uneventful and patient was discharged on the seventh post-operative day. The patient is on follow-up.



**Figure 2** Inflamed appendix is seen lying over the terminal ileum and the tip attached to the ileocecal mesentery resulting in a band like structure causing obstruction

## DISCUSSION

Appendicitis causing intestinal obstruction was described as early as 1901, when Lucius Hotchkiss documented three successful surgeries for intestinal obstruction due to appendicitis.<sup>3</sup> In 1909, Forbes Hawks divided them into mechanical, septic and a combination of the two.<sup>4</sup> Our case was a variable of mechanical without strangulation like the case reported by Naumov in 1936.<sup>4</sup>

Clinically these patients can be classified into two types

1. Predominant features of appendicitis with some evidence of intestinal obstruction. In this group of patients, intestinal obstruction occurs during the phase of active appendicitis.
2. Patients with Acute intestinal obstruction, on laparotomy found to have appendicitis as the cause. In this group, there may or may not be a history of appendicitis. Intestinal obstruction dominates the clinical picture and may completely obscure the underlying appendicular disease. Such cases are

managed accordingly by exploratory laparotomy as in our case and previously documented by Laxminarayan Bhandari.<sup>2</sup>

## CONCLUSION

Intestinal obstruction due to appendicitis is of four types. Clinically and radiologically it may not be possible to differentiate these types. It may be predominantly appendicitis or predominantly intestinal obstruction. In the second group it is important to rule out appendicitis by careful re-evaluation. We found that mechanical bowel obstruction in direct connection with appendiceal inflammation is an extremely rare, but potentially life-threatening complication. A conclusive diagnosis typically has to wait until visualization during the surgical intervention. As such a case presenting with acute intestinal obstruction of unknown etiology, we need to consider appendicitis as a probable cause.

**Consent:** Written informed consent was obtained from the patient for publication of this case report and any accompanying images.

**Conflict of interest:** None Declared.

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**Author Disclosure:** The authors do not have any disclosable interest.

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## CASE REPORT

# Thelaziasis: an emerging ocular parasite in Northeast of India

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## ABSTRACT

*Thelazia spp.* is a parasitic nematode and the most common cause of “thelaziasis” (oriental eye worm infestation) in humans, dogs and cats. It was first discovered in the eyes of a dog in China in 1910. Infection in man is considered zoonosis. Transmission to humans occurs via the face fly (*Musca autumnalis*) in *T. callipaedia* and *Fannia canalicularis* in *T. californiensis*. The eye worm commonly parasitizes the tear ducts and conjunctival sacs of the host although intraocular infestations have been reported. Here, we report a case of thelaziasis in a 36-year-old male, from Majuli, Assam. He had a complaint of ‘something’ inside the left eye since one month. The patient was admitted in the Inpatient Department of Ophthalmology and after thorough observation a mild congestion was noticed in the bulbar conjunctiva of left eye. After two days of exploration a small whitish appearing point was seen in deep upper conjunctival cul- de -sac of left eye which was grasped with a forcep and pulled outwards. On further exploration another worm was noticed inside left upper lid in the sub conjunctival space. In total, three worms were received in the Department of Microbiology which were intact, slender, thread-like and creamy white. Based on the site of recovery, gross appearance and microscopical findings, the worms were identified to be *Thelazia callipaedia*. This study highlights the importance of “thelaziasis” and it required further research to minimize the morbid conditions and sequelae caused by the worm by its presence in the human eye.

**Keywords:** Cul- de -sac; eye worm; Presbyopia; *Thelazia callipaedia*.

## INTRODUCTION

*Thelazia callipaedia* is a parasitic nematode and the most common cause of “thelaziasis” (oriental eye worm infestation) in humans, dogs and cats. It was first discovered in the eyes of a dog in China in 1910.<sup>1</sup> Infection in man is considered zoonosis. Williams first reported human thelaziasis in the United States in 1935. Transmission to humans occurs via

the face fly (*Musca autumnalis*) in *T. callipaedia* and *Fannia canalicularis* in *T. californiensis*.<sup>2</sup> They feed on proteins in eye secretions, nasal secretions and saliva. The flies have rough, spongy mouthparts that are irritating and increase tear production, thus promoting successful transmission. The eye worm commonly parasitizes the tear ducts and conjunctival sacs of the host though intraocular infestations have been reported.<sup>3,4</sup> The eggs of *Thelazia callipaedia* develop into first stage larva (L1), in utero. The female deposit these larvae enclosed in egg membranes in the lacrymal secretions of the host. When the intermediate host (tear feeding fly) feeds, it ingests the *T. callipaedia* larva. Once inside the fly, L1 larva ‘hatch’ from the egg membrane and penetrate the gut wall. They remain in the haemocoel for two days and invade either the fat body or the testes of the flies. In the tissues, they develop into the L3 stage. The L3 migrates into the head of the fly and releases into the eye or its periphery during the next feed. Once in the eye, eyelid, tear gland or ducts of the mammalian host, the L3 larva develop through the L4 larva stage and into adults in about 1 month.<sup>5</sup> Adult worms for both the species are creamy-white and measure upto 0.75X 13.00 mm in males and 0.85 X 17.00 mm in females. The male is identified by the ventral curving of the posterior end and the female is identified by the vulva, which opens mid-ventrally. *T. callipaedia* can be distinguished morphologically from *T. californiensis* based on the numbers of pre and post cloacal papillae in the male and the position of the vulva in the female. Male *T. callipaedia* have 8-10 pairs, *T. californiensis* have 6-7 pairs of precloacal papillae and 5 and 3 pairs of postcoacal papillae respectively. The treatment of human *Thelazia* infection consists of removal of the worm under local anaesthesia.

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Review of literature indicate that of the reports<sup>3,6-11</sup>, available from India on human thelaziasis, three are from the Northeast of India.<sup>7,8,10,12</sup> This is the fourth report from the Northeast in a patient hailing from the plains of a riverine island clearly indicating an apparently increasing trend of the zoonosis in this part of the tropic irrespective of being limited only to hilly and foothill terrains.<sup>11</sup>

### Case report

A 36-year-old male from Majuli, Asia's largest riverine island in Jorhat, Assam attended the Ophthalmology Out Patient Department of a tertiary care hospital with complaint of 'something' inside the left eye since last one month. He also brought a specimen of a foreign body he claimed to have come out of the eye. The patient was apparently healthy, of moderate hygiene and an agriculturist by occupation. He gave a history of some insect entering the eyes while cycling back home from fields in the evening. He also had pet dog and cat at home.

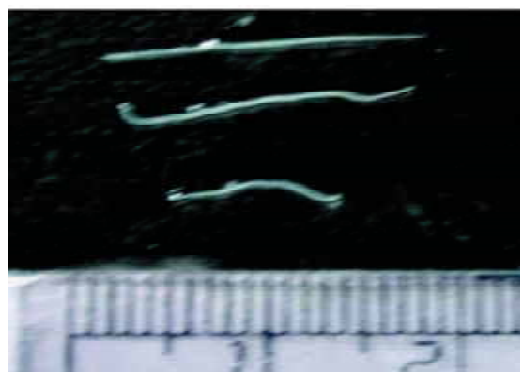
On examination, the visual acuity of the right eye and left eye were 6/6 and 6/9 respectively. Pin hole revealed 6/6 in both the eyes. Near vision was N8. Lids, cornea, anterior chamber, iris, pupils and lens were all normal. Mild congestion was noticed in the bulbar conjunctiva of left eye. Dilated fundoscopic examination revealed a normal retina with normal appearing optic disc, foveal reflex, macula. Peripheral retina also appeared normal. There were no rashes or swelling in the skin.

Haemogram, other parameters, diurnal and nocturnal peripheral blood films were within normal limits. Stool examination revealed no ova. C reactive protein was elevated, ultra sonogram of the left eye revealed a moving structure that could be captured with great difficulty. CT scan (contrast) orbit and brain were within normal limits. The patient was admitted for observation. In subsequent days he complained of 'something' wriggling in his left eye but even after thorough examination several times in the day nothing could be revealed. After two days exploration was done under local anaesthesia. The right eye revealed no abnormalities. A small whitish appearing point was seen in deep upper conjunctival cul-de-sac of left eye which was grasped with a forceps and pulled outwards. A 10 mm size worm was extracted out. At first it was stationary perhaps due to the affect of anaesthetic but slowly it became active. On further exploration after making the lids intermittently avascular by putting chalazion clamps to improve contrast another worm was noticed inside left upper lid in the subconjunctival space. A cataract surgical knife was used to slightly dissect the area where the worm was noticed and forceps was used to grasp and take it out. Thereafter, lacrimal syringing with anaesthetic was done but to no avail. All the worms were sent to the Department of Microbiology for identification. Meanwhile, the patient was put on Albendazole 400 mg and Prednisolone 30 mg to counteract any hypersensitivity reactions. Treatment continued for 7 days. He was discharged after four days when there were no more complaints of foreign body

sensation. The patient was prescribed reading glasses to correct his near vision of Presbyopia.

### Identification

All the three worms received were intact, slender, thread-like and creamy white. Two of these were 20mm and the third was 10mm in length (**Figure 1**).



**Figure1** Showing the length of the worms in mm



**Figure 2** Showing the trapezoid anterior end and striated cuticle (x400)

The maximum breadth was up to 0.25mm. The entire bodies of the worms were covered by dense transverse cuticular striation. The smaller worm had a tapered anterior end with conspicuous, trapezoid buccal capsule (**Figure 2**) with no lips or teeth like structures and ventrally curved posterior end (**Figure 3**).



**Figure 3** Showing coiled posterior end of the male worm (x400)



**Figure 4** Showing the vulval opening anterior to the esophago-intestinal junction

The spiral coiling of the posterior end limited the observation of the preanal and post anal papillae. In the female worms the vulva was anterior to the esophago-intestinal junction (**Figure 4**) and numerous encysted larva were seen in the uterus (**Figure 5**).



**Figure 5** Showing encysted larva in the uterus of the female worm (x 400)

The posterior end was rounded. We tried to irrigate the conjunctiva with 0.85% sterile normal saline to look for eggs and larva in the conjunctival fluid for three consecutive days but to no avail. Based on the site of recovery, gross appearance and microscopical findings, the worms were identified to be *Thelazia callipaeda*.

## DISCUSSION

Reports on human thelaziasis are available from several Southeast Asian countries, including India. Literature review from India suggests the first report to be from Salem district in 1948. Two more cases were reported from the North eastern state of Manipur in 1993. Subsequently, Mukherjee et al in 1978 described an intraocular infestation, Mahanta et. al in 1996 from Assam, Sharma et. al in 2006 from Himachal Pradesh and Nath et. al in 2008 and Handique et al in 2014 again from Assam came across few cases over a span of three decades. The present report is supposed to be the eight in the country and fourth from the northeast clearly indicating emergence of the parasite in this region or under reporting from elsewhere. This report also intends to highlight that geographical topography of mountains and foothills may not

just favour the occurrence of thelaziasis as speculated. The patient in this report hailed from the riverine island and had no history of visit to any mountainous region. Therefore, to restrict or to overlook the epidemiology of human thelaziasis in terms of terrains would be short sightedness from strategic prevention and public health point of view.

## CONCLUSION

The authors are in view that a thorough investigation of the carnivores especially pet dogs and cats which are in close contact with humans and the vectors is a must in the region that shows increasing prevalence of this parasite. Amalgamation of medical microbiologists, veterinarians and entomologists could be a welcome gesture in the venture to minimize the morbid conditions and sequelae caused by the worm by its presence in the human eye.

**Conflict of interest:** No conflict of interest.

**Ethical clearance:** Obtained.

**Consent of the patient:** Both verbal and written consent was obtained from the patient.

**Contribution of authors:** "We declare that this work was done by the authors named in this case report with equal contributions."

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